ABSTRACTS DE TRABAJOS DE INVESTIGACION PRESENTADOS AL
CONGRESO EULAR 2009.

European League Against Rheumatism

Copenhague 10-13 de Junio del 2009

TEMA:  FIBROMIALGIA y/o SINDROME DE FATIGA CRONICA
Background: Fibromyalgia (FM) is characterized by widespread pain and fatigue. Various medical and rehabilitative techniques are used in the treatment of this disorder.

Objectives: To compare the effects of aquatic training and gym exercise versus home exercise on physical and psychological parameters in patients with FM.

Methods: Seventy-five female patients between the ages of 18-50 (35.0±8.8) with FM (American College of Rheumatology criteria) were randomized into three groups: home exercise (Group I, n=25), gym exercise (Group II, n=25) and aquatic training (Group III, n=25). Group I served as controls and performed daily 15 minutes of home exercise. Group II and III attended supervised progressive exercises two times per week. Exercise programs lasted 40 minutes in the first month, 45 minutes in the second month and 50 minutes in the third month. Study period was 12 weeks and assessments were done at baseline and after 12 weeks. The primary outcome measure was pain (visual analog scale, VAS). Secondary outcome measures were health status (fibromyalgia impact questionnaire, FIQ), endurance (6-minute walk test), quality of life (SF-36 physical and mental health scores) and depression (Beck depression inventory).

Results: Patients' characteristics and baseline scores were similar in all three groups. VAS (p<0.001), FIQ (p<0.001), 6-minute walk test (p<0.001) and SF-36 physical scores (p<0.001) showed significant improvements after the exercise program as compared with the baseline values in group II and III than group I, but no statistically significant improvements were found between group II and III. Beck depression inventory scores (p<0.05) and SF-36 mental health scores (p<0.05) was improved in group II and III after the exercise program than group I but improvement was more prominent in group III.

Conclusion: Both aquatic and gym exercises had positive effects on physical and psychological parameters in patients with FM. Aquatic exercises also had additional benefit on depression and SF-36 mental health scores. In light of our results we suggest that these type of exercises could be used in the management of FM patients.

References:


A DOUBLE BLIND CLINICAL TRIAL: TREATMENT OF FIBROMYALGIA IN POST-MENOPAUSAL WOMEN WITH EVISTA

S. Sadreddini1, M. Molaeeefard2, H. Noshad3, M. Ardalan3, A. Asadi3. 1Rheumatology, Tabriz university of medical sciences; 2rheumatology, Tabriz university (medical sciences); 3rheumatology, Tabriz university of medical sciences, Tabriz, Iran (Islamic Republic of)

Background: Raloxifene (Evista) has been found to function as an estrogen antagonist when acting through estrogen receptor $\beta$ on genes containing estrogen response elements but function as a partial agonist when acting on genes through estrogen receptor $\alpha$. It may be as an ideal alternative to hormone replacement therapy. Previous studies have shown that estrogen is strongly implicated in the regulation of mood and behaviour and in the pathobiology of mood disorders. It acts as a psychomodulator during periods of decreased estrogen levels. There are also growing evidences suggesting that estrogen may be efficacious as a sole antidepressant for depressed perimenopausal women (1). A low estrogen level is responsible for affective symptoms, including depressed mood, anxiety, sleep disturbances and fatigue (2). It has been shown that Estrogen can induce the transcription of opiates in estrogen receptor-positive cells derived from the superficial layers of the spinal dorsal horn (3, 4). These endogenous opiates act on enkephalinergic neurons to mediate inhibition of nociceptive relay cells, both in primary afferent fibers as well as in pain-modulating fibers descending from the brainstem (5). Efficacy of testosterone on pain in fibromyalgia (6) is supported by the discovery of aromatase-positive cells in the spinal cord dorsal horn of higher vertebrates (quail), where initial processing of pain sensation occurs (7) and the presence of aromatase, which converts testosterone to 17$_\beta$ estradiol, is very interesting.

Objectives: This study compared Raloxifen (Evista) with placebo in the treatment of fibromyalgia.

Methods: A total of 100 menopausal women with fibromyalgia enrolled from Feb 2005 until Oct 2006 entered a double blind randomized study comparing Raloxifen, and placebo over 16 weeks of treatment. Fifty patients received Raloxifen and 49 (98%) completed the study, 50 received Placebo and 47 (94%) completed the study.

Raloxifen in doses of 60 mg/every other day or identical placebo were given over 16 weeks of follows up. Improved recovery for a treatment group was assessed by a significantly higher mean score from baseline to the end of the treatment trial, compared with patients treated with placebo, on measures of Stanford Health Assessment Questionnaire (HAQ); Iranian version of hospital anxiety and depression questionnaire (IHAD); sleep disturbance; number of tender points; reduction of pain and fatigue based on visual analogue score.

Results: Raloxifen produced a significantly higher response rate than placebo in treating fibromyalgia, in improving pain and fatigue symptoms, reduction in the number of tender points, sleep disturbance and recovery of activities in daily living as measured by the Stanford Health Assessment Questionnaire (HAQ). The mean age of Raloxifen group was lower than placebo group but the mean duration of disease and menopause was not significantly different between them so it doesn't seem that the difference of age can explain the better effect of Raloxifen in this study.

There was no effect of Raloxifen on HAD score among fibromyalgia patients.

Conclusion: Given the doses of medication used in this study, Raloxifen was superior to placebo in the treatment of menopausal patients with fibromyalgia.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):694
WHAT DO FIBROMYALGIA PATIENTS HAVE TO CHANGE TO IMPROVE THEIR QUALITY OF LIFE?

X. Torres¹, A. Collado², A. Arias², A. Conesa². ¹Clinical Psychology; ²Rheumatology, Hospital Clinic i Provincial de Barcelona, Barcelona, Spain

Background: A century after the first description of fibrositis, a definitive treatment of the fibromyalgia syndrome is still lacking. It seems reasonable to suppose, then, that the chronicity of pain and associated symptoms convey a worsening of the fibromyalgia patients’ quality of life. Most of the studies that try to define the determinants of the quality of life in fibromyalgia apply cross-sectional designs that does not allow defining which variables must be modified in order to improve our patients’ quality of life.

Objectives: To analyze by means of a longitudinal prospective design which of the clinical variables amenable to modification is able to better explain the improvement in the fibromyalgia patients’ quality of life, six months after having undergone a multidisciplinary treatment.

Methods: The linear relations between the amount of change observed in several clinical variables susceptible of modification (depression and anxiety, locus of control, intensity of pain, catastrophizing, self-efficacy and fear of pain and of activity) and the changes in each subscale of the quality of life inventory SF-36, were assessed. Those variables that showed a statistically significant linear relation with the SF-36 subscales were included in a multivariate regression analysis.

Results: The sample was composed by 90 patients (women 97.8%) with a mean age of 43.7 (8.7) years, who suffered a fibromyalgia syndrome of 8.6 (7.2) years of duration. The multivariate analyses showed:

a) The reduction of the interference of health on physical activities was explained by the increase in the perception of self-efficacy for performing daily activities and by the reduction of the depressive symptoms (F=8.0; p=0.001; R² corrected=0.15).

b) The reduction of the interference of physical health on the desired ability of performance depended on an increase in the internality of the locus of pain control, on the reduction of the fear of activity and on the reduction of the depressive symptoms (F=7.9; p <0.001; R² corrected=0.31).

c) The increasing perception of self-efficacy to control pain and the reduction of the depressive symptoms explained the improvement of the subjective general health perception (F=9.0; p=0.001; R² corrected=0.27).

d) The increase of the vitality depended on a higher perception of self-efficacy to control the physical symptoms and on the reduction of the fear of activity (F=8.5; p <.001; R² R² corrected=0.15).

e) The improvement of the depressive symptoms conveyed a reduction of the interference of health in the social life (F=16.5; p=0.001; R² corrected=0.26).

f) The improvement of the mental health depended on the reduction of the catastrophizing thinking and the reduction of the fear of activity (F=7.8; p=0.001; R² corrected=0.24).

Conclusion: The reduction of depression, the increase of the self-efficacy and the reduction of the fear of activity partially explain the improvement of the quality of life of fibromyalgia patients six months after receiving multidisciplinary treatment.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):774
HEALTH ECONOMIC COMPARISON OF OUTPATIENT MANAGEMENT OF FIBROMYALGIA BEFORE AND AFTER DIAGNOSIS IN FIVE EUROPEAN COUNTRIES

C. Taieb, M. Lamotte, Y. Maugars, K. Lelay. 1Public health and Quality of life, PFSA, Boulogne Cedex, France; 2IMS Health, Bruxelles, Belgium; 3Rheumatology Department, University Hospital, Nantes, France

Background: The prevalence of fibromyalgia (FM) was estimated at 2.9% (95% CI: 2.4 – 3.4), in the general population in Europe [1]. According to recent studies, patients with FM are high consumers of health care services [2-4]. The early diagnosis and management of FM represents a significant public health issue.

Objectives: To compare the resource use and related costs associated with the treatment of FM patients in five European countries (UK, France, Italy, Spain, Germany).

Methods: The UK resource use data were extracted from medical records of 2,260 patients diagnosed with FM between 1998 and 2003 in the General Practice Research Database (GPRD) [3,4]. For the other countries, a questionnaire was created based on the UK data and local experts, GP and rheumatologists, were asked to compare their own clinical practice to UK prescriptions in terms of tests, drugs, general practitioners and specialists visits, over a period of -4 years before diagnosis to +4 years after the diagnosis of FM. Paramedical and alternative care were also collected for 4 countries, but this information was not available for the UK. The impact of diagnosis was evaluated for each of these medical resources. Resources used were translated into costs (2007 Euros). The societal perspective, including public health care payer contribution and patient co-payments, was used. Inpatient care and productivity loss were not included in these analyses.

Results: Resource use and costs per 100 person-years related to lab tests are the highest in Spain, the UK and Italy, in the year of diagnosis (10,041€ in Spain) and decrease afterwards. In France (4,291€) and Germany the highest cost is seen after diagnosis. Drug costs are highest in Germany and Spain with the highest values seen after diagnosis. Drug costs are higher in Germany (33,027€ vs 6,868€ in France after diagnosis) mainly due to the higher unit costs. Costs related to GP visits increase till diagnosis in Germany (89,206€), the UK, France, and Italy (33,430€). The costs for referrals to specialists are the highest before diagnosis in the UK (13,066€), France, Italy, and Germany (2,764€) after which a constant decrease is observed. Paramedical and alternative treatments are highest the year of diagnosis in France and in Germany (127,794€). In Italy and Spain, complementary treatments are not reimbursed. The highest total cost per patient per year is in Germany (1,068€), the lowest in Italy (351€). The highest patient contribution is in France (157€), the lowest in Spain (13€).

Conclusion: Once a FM patient receives a formal diagnosis, their subsequent healthcare utilisation costs gradually decrease in all of the countries studied. Cost savings are due to the reduction of visits and associated clinical investigations.

References:


Disclosure of Interest: M. Lamotte None declared
Y. Maugars None declared
K Le Lay PFSA
C Taieb PFSA

Ann Rheum Dis 2009;68(Suppl3):690
Background: Efficacy in clinical trials of fibromyalgia can be measured in a variety of ways – using outcomes of pain, sleep, fatigue, fibromyalgia symptoms, anxiety, depression, and various elements of quality of life. Common sense and clinical experience suggest that pain and other benefits go together: substantiating it is rather more difficult.

Objectives: To use individual patient data from clinical trials of fibromyalgia to evaluate correspondence between level of pain relief and benefits in other efficacy variables, and, where possible, compare benefits with normative data.

Methods: Calculation of responder status from baseline using withdrawal, <0% pain relief (worse), 0-15% pain relief (trivial improvement), 15-<30% (minimal), 30-50% (moderate), ≥50% (substantial), irrespective of treatment group. Analysis according to level of pain relief for fatigue, sleep, function, anxiety, depression, and individual domains of SF-36, as well as individual questions relating to ability to work.

Results: Information was available from 4 clinical trials with 2,757 patients receiving placebo or daily pregabalin at 150 mg, 300 mg, 450 mg, or 600 mg maximum. Of these, 899 (33%) were withdrawn, 288 (10%) worse, 366 (13%) benefited trivially, 304 (11%) benefited minimally, 390 (14%) benefited moderately, and 510 (19%) benefited substantially. Moderate and substantial pain benefit was associated with substantially reduced scores (end vs start) for measures of fatigue, fibromyalgia impact questionnaire, MOS sleep scale, sleep disturbance and overall sleep problem index, HADS depression and anxiety, SF36 main domains and and work-related questions from SF36, FIQ and SDS. For HADS anxiety and depression and SF-36 domains, results in patients with substantial pain benefit were close to population normative values. Those with moderate or substantial pain benefit lost one fewer day per week off work.

Conclusion: Those patients with fibromyalgia who benefit most in terms of pain relief (moderate or substantial benefit) also benefit most in all other efficacy measures. The 30% of patients with moderate or substantial pain relief have most of the benefits. Those who have minimal or lesser pain relief have little or no improvement on any other measure. These findings have major implications for clinical practice, since at least 30% pain relief after 4-6 weeks is a watershed, reflecting either response or need to change drug. This also has major implications for health technology appraisal, since it delineates a point beyond which there is sufficient aggregation of benefits to produce economic advantages for all but the most expensive treatments.

Disclosure of Interest: RAM: Grant Research Support, Speakers Bureau, Pfizer; SS: None declared; JP: None declared; SD None declared; HJM: Speakers Bureau

Ann Rheum Dis 2009;68(Suppl3):694
Background: Fibromyalgia is a chronic condition associated with pain, sleep disturbance and disability. Disease related costs are high and effective treatment options few.

Objectives: To evaluate the cost effectiveness of pregabalin in the treatment of fibromyalgia.

Methods: A decision-analytic model was developed comparing pregabalin 300mg or 450mg against placebo, duloxetine 60mg or 120mg, gabapentin, and tramadol. After a 12 week initial treatment phase patients who respond to treatment enter an ongoing treatment phase using a Markov model in which patients maintain response, lose response, or drop out. The base case considered patients with a Fibromyalgia Impact Questionnaire (FIQ) score of >59 and a pain score of >6.5 at baseline. Response rates for pregabalin and placebo were taken from three randomised trials, and a one year open label extension study was used for long term parameters. Response was defined as a 30% improvement over baseline in pain score and a patient global impression of change rating of much improved or very much improved. Relative rate of response for other comparators over placebo were extracted from a systematic review of published randomised controlled studies. The primary effectiveness endpoint was Quality Adjusted Life Years (QALYs). Utilities gain over baseline associated with response and non-response was estimated by applying the SF-6D utility algorithm to SF-36 data collected in the pregabalin trials. Resource use associated with fibromyalgia management was estimated from published studies and costs were estimated from the UK NHS perspective at 2008 prices. Costs and QALYs were discounted at 3.5%. Sub-group analysis considered differing levels of disease severity at baseline and definitions of acceptable response. Non-parametric bootstrapping analysis was used to generate confidence intervals.

Results: In the base case, pregabalin 300mg and 450mg increased cost per patient by £656.14 (95% CI: 565.85 - 758.73) and £666.34 (£573.05 - 772.70) and improved QALYs per patient by 0.03 (-0.04 - 0.10) and 0.03 (-0.05 - 0.11) respectively compared to placebo. The cost per QALY gained (CQG) was £23,173 and £23,540. CQG over placebo for patients with FIQ >59 and no restriction on pain was £26,879 for pregabalin 300mg and £23,053 for 450mg. For patients who had previously received sleep medication CQG was £20,818 for pregabalin 300mg and £25,195 for 450mg. In the base case population CQG for pregabalin 450mg against duloxetine 60mg and 120mg was £19,227 and £14,097, against gabapentin £13,970, and against tramadol £98,101. Sensitivity analysis found the cost-effectiveness of pregabalin to be most sensitive to drug price and response rates.

Conclusion: This model found Pregabalin 300mg and 450mg to be cost-effective using standard UK criteria in patients with fibromyalgia and severe pain.
SYSTEMATIC REVIEW OF SYSTEMATIC REVIEWS OF TREATMENTS FOR FIBROMYALGIA: HOW GOOD IS THE EVIDENCE?

R.A. Moore¹, S. Straube², H. Gaskell¹, S. Derry¹, H.J. McQuay¹. ¹Pain Research and Nuffield Department of Anaesthetics, University of Oxford, Oxford, United Kingdom; ²Department of Occupational and Social Medicine, University of Göttingen, Göttingen, Germany

Background: Trials of low quality, lacking validity, or with small numbers of patients and events are features known to over-estimate effects of treatment, as do systematic reviews that include such trials [1]. IMMPACT recommendations [2] are that ≥30% pain relief or moderate improvement on Patient Global Impression of Change constitute moderate benefit, and that ≥50% pain relief or very much improvement constitute substantial benefit.

Objectives: 1: To examine published systematic reviews of interventions for fibromyalgia and evaluate the credibility and robustness of the evidence for each intervention. 2: To compare interventions reporting numbers with moderate or substantial benefit where adequate data were available. 3: To supplement reviews with data from large high quality RCTs.

Methods: Systematic search of electronic databases for systematic reviews of any intervention or combination of interventions for treating fibromyalgia. Assessment of trial duration allowed, outcomes used, numbers of trials and patients, and whether trials of low reporting quality were included. Large, randomised, placebo-controlled trials were also sought.

Results: Thirty systematic reviews were identified: 4 general reviews, 14 examining pharmacological, and 12 non-pharmacological interventions. Common problems were inclusion of low quality trials, short duration, and small numbers. Twenty reviews presented a positive conclusion, and six more were strongly positive; three were negative. On evidence presented it was possible to agree only with three positive conclusions relating to pregabalin and duloxetine, and two negative conclusions relating to multidisciplinary rehabilitation and acupuncture.

Information on outcome of moderate or substantial benefit was available from systematic reviews or large high quality trials for pregabalin (1940 patients), milnacipran (1321), duloxetine (996), amitriptyline (342), and tramadol plus paracetamol (313). Response rates for substantial benefit varied substantially between trials: as low as 7% in those of milnacipran, and 21% for those of duloxetine. At most only 1 in 3 patients had substantial benefit with active drug. NNTs for at least 50% pain relief were: pregabalin 10 (95% confidence interval 7.4-16), milnacipran 18 (11-43), duloxetine 6.4 (4.7-9.9), amitriptyline 4.8 (3.4-8.3), tramadol plus paracetamol 6.2 (3.9-15). Only milnacipran was significantly worse than amitriptyline.

Conclusion: The evidence base for treatment of fibromyalgia is weak. Of 26 reviews with positive conclusions, evidence supported only three, for two pharmacological interventions based on large datasets in modern trials that fulfilled criteria of quality, validity, and size. Most reviews had significant failings of quality, validity, and size, all of which tend to overestimate treatment efficacy. Drug treatments where there is an adequate amount of evidence indicate that only about a third of patients with fibromyalgia achieve substantial benefit.

References:


Disclosure of Interest: RAM: Grant Research Support, Speaker Bureau, Pfizer; SS: None declared; HG: None declared; SD: None declared; HJM: Speakers Bureau

Ann Rheum Dis 2009;68(Suppl3):694
INCREASED GLUTAMATE COMPOUNDS IN THE BRAIN OF PATIENTS WITH FIBROMYALGIA: A MR SPECTROSCOPY STUDY

A. Collado1, M. Valdes2, N. Bargalló3, M. Vazquez2, L. Rami2, E. Gomez1, M. Salamero2.
1Fybromyalgia Unit. Rheumatology Service. ICEMEQ; 2Institut Clinic of Neurosciences; 3Imaging Department.CDI, Hospital Clinic of Barcelona, Barcelona, Spain

Background: Fibromyalgia (FM) has been defined as a systemic disorder clinically characterised by pain, cognitive deficit and the presence of associated psychopathology, all of which are suggestive of a primary brain dysfunction. Recently, some spectroscopy differences was found in the hippocampi of FM patients (1,2) and a relationships between the levels of brain metabolites in the insula and prefrontal cortex and the severity of clinical and experimental pain has been observed (3).

Objectives: In order to identify the nature of this cerebral dysfunction, brain metabolites of FM patients have been studied through MR spectroscopy techniques.

Methods: Brain metabolites (Choline (Cho); Myo-inositol (In); Creatine (Cr); Glutamate+glutamine (Glx); N-acetylaspartate (NAA)) in amygdala, thalami and prefrontal cortex were studied through MR spectroscopy techniques in a sample of 30 women with FM, and in a control group of healthy women (n=30) of the same age (42.6±8.7 vs 43.8±10.6). For the quantification of absolute concentrations in mmol/kg wet weight, we used the user-independent frequency domain-fitting program LCModel (4) Clinical assessment of patients included demographic variables, time of disease evolution, pain and fatigue intensity (Visual Analogue Scale), number of tender points, perceived disability (Health Assessment Questionnaire), health status (Fibromyalgia Impact Questionnaire) and anxiety and depression state (Hospital Anxiety Depression Scale).

Results: Compared to healthy controls FM patients showed higher levels of glutamate compounds (Glx) in the right amygdala (t=2.08, df 48, p=0.004) and a higher glutamine-glutamate/creatine ratio (Glx/Cr) in the left thalamus (t=2.426, 53 df, p=0.01). The higher Glx levels in the left thalamus of patients were related to fatigue (r=0.463, p<0.05) and pain intensity (t=2.347, df 25, p=0.02). Also, in FM patients with more pain and fatigue inositol (Ins) levels were significantly higher in the right amygdala (pain,r=0.502, p<0.01, fatigue r=0.589, p<0.01) The Ins levels was correlated with time of evolution and disability in the left amygdala (r=0.435, p<0.05, r=-0.630, p<0.01 respectively).

Conclusion: The distinctive metabolic features found in the right amygdala and left thalamus of FM patients suggest the possible existence of a neural dysfunction in emotional processing, this being a prolongation of the dysfunction in pain processing previously proposed by some authors.

References:

4. Provencher SW. Automatic quantification of localized in vivo 1H spectra with LCModel. NMR Biomed 2001;14:260-264

Disclosure of Interest: none declared
PRODUCTION OF NITRIC OXIDE (NO) BY GRANULOCYTES IN FIBROMYALGIA

1Rheumatology, Hospital Santa Casa de Belo Horizonte; 2Biochemistry and Immunology,
Universidade Federal de Minas Gerais; 3Núcleo de Pós-Graduação e Pesquisa, Hospital Santa Casa
de Belo Horizonte, Belo Horizonte, Brazil

Background: Fibromyalgia (FM) is a generalized chronic pain syndrome (1). Central sensitization
contribute to or are responsible for FM pain (2). Nitric oxide (NO) may play an important role. The NMDA
activation induces calcium entry into the dorsal horn neurons (3), leading to the synthesis of NO (4). NO
can enhance the release of sensory neuropeptides (substance P) contributing to the development of
hyperalgesia and maintenance of central sensitization (5). Correlation between serum NO level and pain in
FM patients were seen in a controlled study (6).

Objectives: Investigate the production of nitric oxide (NO) by granulocytes from patients with FM.

Methods: Twenty patients (ACR criteria), 18 women and 2 men, with ages ranging from 20 to 40 years
(mean value 32.6 years) and sex- and age-matched healthy volunteers were selected. All participants
presented normal clinical and laboratory test evaluations. None of the FM group had used medications
(except paracetamol) during the 2 week period prior to the commencement of the study. Granulocytes
were purified from 10.0 mL samples of heparinised venous blood and incubated in a humidified
atmosphere of CO2 for 16 h at 37°C. The cell-free supernatants were collected and nitrite concentration
determined and the results were expressed as micromolar (µM) nitrite.

Results: The production of NO (expressed in µM nitrite) by granulocytes from FM patients was 24.5 times
greater than that of cells from healthy subjects.

Conclusion: Results of the present study indicate that NO synthesis in granulocytes from FM patients is
elevated. This should encourage further researches, evaluating the potential role of NO in the
pathophysiology of FM.

References:

1. Yunus MB. Fibromyalgia syndrome: clinical features and spectrum. In: SR Pillemer, ed. The
fibromyalgia syndrome: current research and future directions in epidemiology, pathogenesis, and
2. Clauw DJ, Chrousos GP. Chronic pain and fatigue syndromes: overlapping clinical and
neuroendocrine features and potential pathogenic mechanisms. Neuroimmunomodulation 1997
3. Bennett GJ. Update on the neurophysiology of pain transmission and modulation: focus on the
4. Meller ST, Gebhart GF. Nitric oxide (NO) and nociceptive processing in the spinal cord. Pain
1993 (52):127–136
6. Sendur OF, Turan Y, Tastaban E, Yenisey C, Serter M. Serum antioxidants and nitric oxide levels

Disclosure of Interest: None declared.
Background: Fibromyalgia syndrome (FM) is a chronic multi-symptom disease, with pain being possibly the most important symptom. One of the main factors hampering the clinical assessment of FM is the lack of objective physical examination or laboratory diagnostic test findings confirming its severity. The absence of physiological markers of disease activity also complicates the clinical decision-making process.

Objectives: To analyse the psychometric properties of the self-administered Fibromyalgia Activity Score (FAS) within a population of patients with FM.

Methods: The psychometric properties of FAS were tested in 226 FM patients (209 women, 17 men) with a mean age of 52.1±10.8 years, and a mean duration of symptoms of 10.5±9.7 years (range 1-28 years), whose disease-related characteristics were assessed by means of patient 11-numbered circle VAS for pain, fatigue, sleep disturbance, and general health (GH), the tender point score (TPS), the Self-Assessment Pain Scale (SAPS), the Fibromyalgia Impact Questionnaire (FIQ), and the Medical Outcomes Study SF-36 Health Survey (SF-36). A group of 226 patients satisfying the ACR criteria for rheumatoid arthritis was used for comparative purposes. Of the 179 FM patients who entered the follow-up study, 152 were included in the responsiveness analyses. One hundred and sixty-three patients repeated the FAS questionnaire after an interval of one week, and its test/retest reliability was calculated using concordance correlation coefficients (CCCs) and Bland and Altman's method. Construct validity was assessed using factor analysis, the Kruskal-Wallis test, Wilcoxon's test, Spearman's correlations, and receiver operating characteristic (ROC) curves; responsiveness was evaluated on the basis of effect size and the standardised response mean.

Results: The FAS fulfilled the established criteria for validity, reliability and responsiveness. When testing its internal construct validity, factor analysis showed that two components (eigenvalues: 1.577 and 1.028) contributed to the total score and explained 86.83% of the cumulative variance. As expected, higher significant correlations were found when comparing FAS with total FIQ (rho= 0.817; p<0.0001) and the FIQ subscales, particularly fatigue (rho= 0.847; p=0.0001), tiredness (rho= 0.742; p=0.0001) and pain (rho= 0.642; p<0.0001), but the correlation between the FAS and SF-36 MCS (rho= - 0.502; p<0.0001) was particularly interesting. Test-retest reliability was satisfactory, with CCCs of 0.850 confirmed by Bland-Altman plots. The magnitude of the responsiveness measures was statistically different between the FAS (0.984±0.911) and the FIQ (0.781±0.915; p = 0.034), and between the SF-36 MCS (0.434±1.132; p<0.01) and PCS (0.321± 1.116; p<0.001) summary scores.

Conclusion: Our data suggest that the self-administered FAS is a reliable, valid and responsive disease-specific composite response measure for assessing treatment effect in patients with FM, and is suitable for use in clinical trials and everyday clinical practice. Its generalisability and usefulness in assessing treatment and long-term outcomes now need to be evaluated in broader settings.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):693
Background: Although some psychosocial factors have been related with sick leave situation in the patients with Fibromyalgia (FM), we do not know about studies that analysed job description in patients with this situation.

Objectives: To know the differences in the occupational profile of patients with FM who are in sick leave situation.

Methods: 484 patients (96% women with mean age 43±2 years diagnosed of FM (criteria ACR) evaluated consecutively, we detected 345 patients in temporary sick leave situation and 139 patients on active labor situation. We collected the following variables from all patients: Demographical: (Age, Sex, Level Education, Marital Status), Clinical: (Diagnosis Psychiatric (DSM-IV), Level of Pain (EAV) with Pain Visual Analogue Scale, Fatigue (EAV) with fatigue Visual Analogue Scale, Number of Tender Points, Sleep Disturbance, perceived Disability with Health Assessment Questionnary (H.A.Q) and health status with Fibromyalgia Impact Questionnary (F.I.Q.) Occupational: Variables were recorded by standardized interview: Profession; Company Classification; Age of Occupational Beginning; Occupational Satisfaction, Type of Activity; Type of predominant Position; usual hand Prehension; Ergonomic use of tools and materials; presence of unstable Surfaces; Kinetic Chain; Effort Degree, repetition, frequency and duration of the Tasks. We have done a comparative analysis of the variables studied among the patients who are in situation of sick leave and those who are in active labor.

Results: Demographic Variables: differences in sex or age were not observed, there was more married patients in sick leave situation (76,5%vs 53% p<0.05) and had a smaller educational level than active patients ( Primary Studies: 45% vs. 24% and University studies 17% vs. 29% respectively, p<0.05). Clinical Variables: Pain Levels, fatigue and number of sensitive points were similar, but patients in sick leave situation presented an higher degree of disability (mean HAQ, 1.9 vs. 1.6, p<0.05). Occupational Variables: Although some differences in the distribution according to the industrial sectors were observed, these were not outstanding. Patients in sick leave situation began their working life (< 16 years) before actives (88% vs. 67%, p<0.05), and presented higher job dissatisfaction (25% vs. 9%, p<0.05) too. Also it was observed that patients in sick leave situation have, regarding active patients, a greater proportion of the following variables: Physical activities over intellectuals (45% vs. 35%, p<0.05). Heavy physical efforts in previous labour activities (40% vs. 29%, p<0.05). Predominant bipedestation static labour positions (48% vs. 37%, p<0.05), Not use of ergonomically tools (61% vs. 45%, p<0.05), hand type prehension (47% vs. 32%, p<0.05), Closed kinetic chains (75% vs. 65% p<0.05), higher activity effort (13% vs. 7% p<0.05) higher task frequency (33% vs. 24%, p<0.05).

Conclusion: People with Fibromyalgia in sick leave situation are characterized for having a lower educational level, greater proportion of married and a labour profile characterized by an early working life, of greater physical nature, worse ergonomic utilization and greater effort and frequency of the tasks carried out, than patients with FM in active labour situation. These variables should be kept in mind in Labour Health Prevention Services in patients with this illness.

Disclosure of Interest: None declared

Background: In most chronic pain conditions only a minority of patients achieve good levels of pain relief with a particular treatment, but clinical trials typically report population average results. IMMPACT recommendations [1] are that ≥30% pain relief or moderate improvement on Patient Global Impression of Change (PGIC) constitute moderate benefit, and that ≥50% pain relief or very much improvement constitute substantial benefit. Suggestions of what constitutes equivalent benefit in other efficacy measures used in fibromyalgia trials have not been made.

Objectives: To test the value of IMMPACT recommendations by analyzing data at the level of the individual patient from four classic randomised, double-blind, placebo controlled trials of pregabalin lasting eight to 14 weeks. To examine response for other efficacy outcomes, including fatigue, fibromyalgia symptoms, anxiety, depression, and individual domains of SF-36.

Methods: Calculation of responder status from baseline using any improvement (≥0%), minimal improvement (≥15%), moderate improvement (≥30%), substantial improvement (≥50%), and extensive improvement (≥70%). Dropouts were assigned 0% improvement from then on. Application to pain, sleep, and other efficacy outcomes.

Results: Information was available on 2,757 patients. Responder analysis for pain intensity and sleep showed progressively fewer responders with increasing level of response. For pain and sleep after 12 weeks of treatment with pregabalin 600 mg maximum daily dose, about 50% of patients achieved any improvement, 40% minimal improvement, 35% moderate improvement, 26% substantial improvement and 12% extensive improvement. Substantial and extensive response took 4-6 weeks to achieve a maximum, and then stayed constant. For pain and sleep a moderate response at 12 weeks was achieved by 21-24% of patients with placebo, and 26-39% with pregabalin 300-600 mg. A substantial response was achieved by 12% of patients with placebo and 17-26% with pregabalin 300-600 mg. PGIC showed more minimal response and less substantial response than change in pain score. Shorter duration and use of any improvement tended to over-estimate treatment effect compared with longer duration and outcomes using higher levels of response. Only for measures of sleep, pain, and vitality was there a significant difference between pregabalin and placebo, in contrast to analysis of average results.

Conclusion: Responder analysis is possible using individual patient data from fibromyalgia trials. While a small proportion of patients has a substantial response, it seems to be consistent over time, at least up to 12 weeks. Responder analysis using efficacy outcomes other than pain and sleep was largely insensitive. Interventions tested in short duration trials using 'any improvement' as an outcome are likely to overestimate the effect of treatment compared with longer duration trials using more clinically relevant outcomes of moderate or substantial improvement.

References:


Disclosure of Interest: RAM: Grant Research Support, Speakers Bureau Pfizer; SD: None declared; SS: None declared; HJM: Speakers Bureau Pfizer

Ann Rheum Dis 2009;68(Suppl3):693
DAY-TO-DAY PAIN RELIEF WITH MILNACIPRAN IN FIBROMYALGIA PATIENTS: RESULTS FROM 2 CLINICAL TRIALS

P. Mease¹, R.H. Palmer², W. Chen³, M.R. Hufford⁴. ¹Rheumatology and Internal Medicine, Seattle Rheumatology Associates and Swedish Medical Center, Seattle; ²Clinical Development; ³Biostatistics, Forest Research Institute, Jersey City; ⁴Clinical Development, Cypress Bioscience, Inc., San Diego, United States

Background: Fibromyalgia (FM) is characterized by chronic widespread pain which can fluctuate markedly in intensity from day-to-day. Thus, an important therapeutic goal in FM is to substantially increase the number of days that patients experience pain relief over an extended time. Milnacipran, a dual reuptake inhibitor with preference for norepinephrine reuptake over serotonin, is approved for the treatment of FM in the United States. Milnacipran has demonstrated efficacy in treating the pain and other symptoms of FM in 2 double-blind, placebo-controlled, phase 3 trials in FM patients.

Objectives: Using pain data recorded daily from patient electronic diaries (e-diaries), milnacipran's day-to-day effects on pain during these 2 studies were examined.

Methods: Data from 2 randomized, double-blind, placebo-controlled FM trials were pooled and analyzed. FM patients (N=2084) were randomized to receive placebo (n=624), milnacipran 100 mg/day (n=623), or milnacipran 200 mg/day (n=837) for 15 or 27 weeks. Pain was assessed by a 24-hour recall VAS pain scale (0-100) collected daily using e-diaries. Days with meaningful pain relief were defined as days that patients reported ≥30% or ≥50% improvements from their mean baseline pain score. The effect of milnacipran treatment versus placebo on the proportion of days with meaningful pain relief was analyzed based on the population of patients who completed at least 15 weeks of double blinded treatment.

Results: Patients treated with milnacipran achieved ≥30% pain reduction in 46% (200 mg/day) and 45% (100 mg/day) of days during the 3-month period compared to 33% of days for placebo patients (P<0.0001, both doses). Similarly, patients treated with milnacipran achieved ≥50% pain reduction in a significantly greater proportion of days with 200 mg/day (29% of days) and 100 mg/day (27% of days) compared to placebo (18% of days; P<0.0001, both doses).

Conclusion: In conclusion, FM patients treated with milnacipran experienced more days of meaningful pain relief over a 3-month treatment period than patients on placebo.

References:


R.H. Palmer, Forest Research Institute, Employee
W. Chen, Forest Research Institute, Employee
M.R. Hufford, Cypress Bioscience, Inc., Employee

Efficacy of Milnacipran 200 mg/day in Fibromyalgia Patients Who Were Nonresponders to Milnacipran 100 mg/day: Results from a 6-Month, Randomized, Double-Blind, Extension Study

P. Mease¹, R.H. Palmer², L. Hallman³, R.M. Gendreau⁴. ¹Rheumatology and Internal Medicine, Seattle Rheumatology Associates and Swedish Medical Center, Seattle; ²Clinical Development; ³Biostatistics, Forest Research Institute, Jersey City; ⁴Clinical Development, Cypress Bioscience, Inc., San Diego, United States

Background: The efficacy of milnacipran for the treatment of fibromyalgia (FM) has been proven in 5 placebo-controlled clinical trials. FM patients receiving milnacipran 100 mg/day or 200 mg/day demonstrated statistically significant improvements over placebo in pain, patients' global impression of change (PGIC) in their FM, and physical functioning. However, it is unknown whether increasing the milnacipran dose from 100 mg/day to 200 mg/day in treatment nonresponders will result in greater therapeutic benefit.

Objectives: This post hoc analysis evaluated the treatment effect of milnacipran 200 mg/day on pain and PGIC measures in FM patients who were classified as nonresponders to milnacipran 100 mg/day at the end of a 6 month, placebo-controlled, lead-in study.

Methods: A total of 92 FM patients who had received milnacipran 100 mg/day for 6-months in the lead-in study were re-randomized to milnacipran 200 mg/day for an additional 6-months as part of a dose blinded extension study. Data from the non-responder subset were analyzed to determine if responder status was achieved when their dose was increased to milnacipran 200 mg/day during the extension study. Of these 92 patients, 36 were defined as pain non-responders at the end of the lead-in study, reporting <30% improvement from their lead-in study baseline pain score. 40 were global non-responders rating their global FM status as no better than 'somewhat improved' at the completion of the lead-in study. To qualify as a pain responder in the current analysis, patients had to report a ≥30% improvement from the extension study baseline on paper VAS 24-hour recall pain scores. To qualify as a PGIC responder, patients had to report that their FM was either 'very much improved' or 'much improved' relative to the beginning of the extension study.

Results: After switching from milnacipran 100 mg/day to 200 mg/day, 45.7% (16/35) of pain nonresponders achieved a ≥30% reduction in pain relative to extension study baseline by the first visit (Week 8). During Weeks 14 to 28 of the extension, pain responder rates among continuing patients ranged from 39.1% (9/23) to 43.3% (13/30). The proportion of patients achieving responder status on the PGIC after switching to 200 mg/day in the extension study ranged from 18% (7/39) at the first visit to 48% (12/25) at the final visit.

Conclusion: Improvements in self-reported pain and overall global status of FM were observed among many patients switched from milnacipran 100 mg/day to 200 mg/day even after several months of treatment. These results suggest that FM patients who do not respond to milnacipran 100 mg/day may benefit from an increased dose of 200 mg/day.

References:


R.H. Palmer, Forest Research Institute, Employee
L. Hallman, Forest Research Institute, Employee
R.M. Gendreau, Cypress Bioscience, Inc., Employee

SAT0466] DEFI (DETERMINATION DE L'EPIDEMIOLOGIE DE LA FIBROMYALGIE) A FRENCH PREVALENCE STUDY OF FIBROMYALGIA

M. Kosa¹, P. Ravaud², L. Pichot², D. Servant⁴, S. Perrot⁶, E. Vicaut⁶, ¹Outcomes research, Pfizer; ²Epidemiology, Groupe Hospitalier Bichat; ³Medical, Pfizer, Paris; ⁴Psychiatry, Clinique Michel Fontan, Lille; ⁵Rheumatology, Hôpital Dieu; ⁶Pharmacology, Hôpital Fernand Widal, Paris, France

Background: Fibromyalgia (FM) is a chronic debilitating condition which mostly affects women. Prevalence data are scarce in France.

Objectives: To determine FM prevalence in a French general population setting.

Methods: A cross-sectional survey in a general population setting was conducted in France. This study partially reproduced the London Fibromyalgia Epidemiology study (LFES) design(1) with a general population screening and the clinical assessment of screened positive subjects. The French study was conducted in 5 different geographic areas: 3 midsize cities, Paris inner suburb and a rural area. In a 1st phase, a telephone screening was carried out on a randomly selected sample of 6,000 households equally distributed, using the validated French version of London Fibromyalgia Epidemiological Study Screening Questionnaire or LFES-SQ (1). In a 2nd phase, when screened positive, subjects were invited to consult a specifically trained rheumatologist. Thus, subjects were identified as FM cases if they met the 1990 ACR criteria(2).

Results: Of 3081 polled subjects, 232 (7.5%) were screened positive: 61.1% female and 28.2% male. Mean age was 61.8 IC95 [59.5;64.0] years. Of them, 96 subjects(41.4%), 70.8% females and 29.2% males with a mean age of 58.2 IC95 [55.2;61.2] years agreed to be examined and went to consultation. Finally 20 subjects (20.8%), 17 women and 3 men, met the ACR criteria and were considered as FM patients. Mean number of myofascial trigger points (MTPS) was 13.0±1.7.

No geographical trends were observed either during the screening or the consultations.

FM prevalence in this study was estimated to 1.5% CI95 1.1;2.0%; it was calculated as follows:

\[
\text{Prevalence (\%) = } \frac{\text{N diagnosis} + \left( \frac{\text{N diagnosis}}{\text{N consultations}} - \frac{\text{N refusals}}{\text{N screened}} \right) \times 100}{N}\n\]

N Refusals: screened positive patients who refused to consult, N diagnosis: clinically confirmed FM patients.

Conclusion: The prevalence of 1.5% for FM in this study as well as demographic characteristics (sex and age) are consistent with other studies data. However it is lower compared to the LFES study figures (2.7%). Less French subjects agreed to be examined; of them, ACR criteria-based FM prevalence was lower. We assumed that those discrepancies are attributable to factors like patient's easier access to specialists and stricter physician's interpretation of ACR criteria.

References:
1. White KP; J Rheumatol 1999 26: 1570-1576
2. Wolfe W; Arthritis & Rheumatism 1990 33: 160-172

Disclosure of Interest: P. Ravaud - Scientific Committee Coordinator
E. Vicaut - Scientific Committee
S. Perrot - Scientific Committee
M. Kosa - Pfizer employee
L. Pichot - Pfizer employee

Ann Rheum Dis 2009;68(Suppl3):693
Background: Fibromyalgia (FM) is a chronic non-inflammatory musculoskeletal disorder characterised by widespread pain and by the presence of at least 11 out of 18 specific tender points on physical examination. Currently no validated laboratory biomarkers are available for FM and the diagnosis of the disease remains exclusively clinical.

Objectives: This study was therefore aimed at assessing the salivary proteomic profile of FM patients in order to identify any possible diagnostic salivary biomarker for the disease.

Methods: Fifteen females (mean age 42.55±11.30 yrs, M±SD) all fulfilling the ACR criteria for FM were enrolled in this study and 15 healthy volunteers with similar demographic characteristics were included as controls. Proteomic analysis was carried out by combining two-dimensional electrophoresis (2DE) and matrix-assisted laser desorption/ionization time-of-flight-mass spectrometry (MALDI-TOF-MS). 2DE was performed using the Immobiline-polyacrylamide system with pH 3-10L, 18 cm long IPG strips. The second dimension (SDS-PAGE) was carried out by transferring the proteins to 12% polyacrylamide gel. The analytical gels were stained with ammoniacal silver nitrate and images were analysed with Image-Master2DPPlatinum. Protein spots from each gel were detected, edited manually and matched automatically. Protein spots of interest were identified by MALDI-TOF. Statistical analysis was conducted by using the student-t test (p-value <0.05).

Results: The analysis of the obtained protein profiles allowed us to observe a good overlapping of representative salivary protein within the two groups. In particular, a-amylase, albumin, actin, carbonate anhydrase VI, keratin 6-L, were not differentially expressed in FM patients with respect to healthy volunteers. Nonetheless, the most relevant observation which emerged from the data analysis was the exclusive and significant over expression of transaldolase and phosphoglycerate mutase 1, two enzymes involved in the pentose shunt and in the glycolysis, respectively. These data could be justified considering that patients with fibromyalgia are exposed to oxidative stress and this increased oxidative stress may play a role in the etiopathogenesis of the disease.

Conclusion: These preliminary results demonstrated the utility of salivary proteomic analysis in the identification of salivary biomarkers in FM patients and in clarifying some of the pathogenetic aspects of the disease. Further studies are necessary to evaluate the potential therapeutic implication of our results in the different subsets of FM patients.

Disclosure of Interest: none declared

Ann Rheum Dis 2009;68(Suppl3):691
Background: Fibromyalgia (FM) and systemic lupus erythematosus (SLE) can share similar symptomatology, at least in some aspects, e.g. pain, fatigue, mood alteration or sleep problems. Association of FM and SLE is reported to be relatively frequent, but in a clinical practice often underdiagnosed. In such a case the concomitant FM could lead to misinterpretation of SLE activity.

Objectives: To examine the impact of concomitant FM on the disease activity, the quality of life and the function in the patients with SLE.

Methods: 91 consecutive pts (85 females, 6 males) with SLE (ACR criteria, 1997) attending our rheumatology outpatient and inpatient department were examined on the presence of FM (ACR criteria, 1990). FM tender points assessment was based on the Standardised Manual Tender Point Survey (1996). The following data were recorded: demographic data, disease activity (SLEDAI), tender point count (TPC), contemporary treatment and laboratory parameters (erythrocyte sedimentation rate ESR, ANA/IF, anti dsDNA/IF, C3, C4). All the patients filled up these questionnaires: Short Form 36 items (SF-36), Health Assessment Questionnaire (HAQ), Fibromyalgia Impact Questionnaire (FIQ), Zung’s self-rating depression scale (SDS).

Results: FM was found in 10 (11%) pts with SLE (SLE/FM pts), all were females. SLE and SLE/FM pts did not differ in age, SLE duration, SLEDAI (3.91 ± 4.1 vs. 3.89 ± 4.1), ESR, ANA, anti dsDNA positivity. SLE/FM pts had significantly higher score of TPC (13.3 ± 2.5 vs. 3.5 ± 3.6), VAS pain (58.4 ± 18.7 vs. 22.9 ± 25.3), VAS fatigue (62.4 ± 26.3 vs. 43.3 ± 30.7), VAS stiffness (43.3 ± 30.6 vs. 17.1 ± 20.4). QOL (SF-36) and disability (HAQ) in SLE/FM pts were significantly worse. Patients with lupus duration over 5 years had FM prevalence 14.3% vs. 3.6% in the group with duration below 5 years. 2.3% of SLE pts had widespread pain without sufficient number of tender points and 7.1% SLE pts had 11 or more tender points but without diffuse pain.

Conclusion: Concomitant FM could be the important factor influencing SLE clinical manifestation and leading to the significant reduction of QOL and to disability independently on SLE activity. Concomitant FM should be considered especially in the long-term duration of SLE.

Disclosure of Interest: none declared
ECONOMICAL COSTS ASSOCIATED WITH THE DIAGNOSIS OF FIBROMYALGIA IN SPAIN

J. Rivera\(^1\), J. Rejas\(^2\), J. Esteve-Vives\(^3\), M. Vallejo\(^4\). \(^1\)Unidad de Reumatología, IPR. Hospital Universitario Gregorio Marañón; \(^2\)Laboratorios, Pfizer, Madrid; \(^3\)Sección de Reumatología, Hospital General Universitari d’Alacant, Alicante; \(^4\)Departamento de Psicología de la Personalidad, Evaluación y Tratamientos Psicológicos, UNED, Madrid, Spain

**Background:** Fibromyalgia (FM) patients have been regarded as great users of health care resources, with important disease-related costs.

**Objectives:** The aim of this study is to describe the economical costs of FM from the perspective of the National Health System in Spain.

**Methods:** This is a multicentric, transversal study of a cohort of patients attended in specialized rheumatology clinics all over the country (ICAF study). The study was conducted on patients fulfilling ACR classification criteria for FM and was based on a face to face patient interview. Data about demographic and clinical variables, physical examination, self-perceived health, psychosocial variables and health resource utilization, were collected. Direct and indirect costs were calculated, and a correlational study between costs and clinical variables was performed.

**Results:** ICAF study cohort is composed of 301 patients (female 96.7%), with a mean age of 49 years and a mean evolution time of pain of 11 years. During the year 2006 the mean total cost per patient per year was 9,982 Euros, with a distribution showed in Table 1. Patients with higher total costs showed the greatest disease involvement. The variables associated with total health care costs were functional capacity, depression, comorbidities and age. Patients with permanent working disability were the greatest resource users with higher total costs.

<table>
<thead>
<tr>
<th></th>
<th>Mean (Euros)</th>
<th>Total (%)</th>
<th>Subtotal (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL COSTS</td>
<td>9982</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>HEALTH CARE COSTS</td>
<td>3246</td>
<td>32.5</td>
<td>100.0</td>
</tr>
<tr>
<td>Medical visits</td>
<td>847</td>
<td>8.5</td>
<td>26.1</td>
</tr>
<tr>
<td>Compl. tests</td>
<td>473</td>
<td>4.7</td>
<td>14.6</td>
</tr>
<tr>
<td>Non-drug therapies</td>
<td>1368</td>
<td>13.7</td>
<td>42.2</td>
</tr>
<tr>
<td>Drug therapies</td>
<td>439</td>
<td>4.4</td>
<td>13.5</td>
</tr>
<tr>
<td>Other*</td>
<td>118</td>
<td>1.2</td>
<td>3.6</td>
</tr>
<tr>
<td>INDIRECT COSTS</td>
<td>6736</td>
<td>67.5</td>
<td>100.0</td>
</tr>
<tr>
<td>Reduced work hours</td>
<td>913</td>
<td>9.1</td>
<td>13.5</td>
</tr>
<tr>
<td>Sick leave</td>
<td>3556</td>
<td>35.7</td>
<td>52.8</td>
</tr>
<tr>
<td>Permanent disability</td>
<td>2267</td>
<td>22.7</td>
<td>33.7</td>
</tr>
</tbody>
</table>

*Includes: Hospital admission costs and utilization of paramedicinal products.

**Conclusion:** FM patients with higher costs show the greatest disease involvement. Both, direct and indirect costs are well correlated to disease severity. The indirect costs account for most of the economic burden of FM and approximately double the health care costs. Patients with permanent working disability present more severe disease and generate greater health care costs.

**Disclosure of Interest:** Pfizer laboratories. Grant Research Support Ministerio de Sanidad (Spain), FIS PI 07/0202. Grant Research Support Grupo ICAF (corporate authors)

Ann Rheum Dis 2009;68(Suppl3):689
SAT0453 | CAN DAS28 BE USED TO MEASURE DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS AND CONCOMITANT FIBROMYALGIA?


1Rheumatology, Tampere University Hospital, Tampere, Finland; 2Rheumatology, New York University Hospital for Joint Diseases, New York, United States; 3Rheumatology, University of Genova, Genova, Italy; 4Rheumatology, University Medical Center Utrecht, Utrecht, Netherlands; 5Rheumatology, Universidade Estadual de Sao Paulo, Sao Paulo; 6Rheumatology, Universidade Federal do Ceará, Fortaleza, Brazil; 7Rheumatology, Copenhagen Univ Hospital at Hvidovre, Hvidovre, Denmark; 8Rheumatology, Hôpital Lapeyronie, Montpellier; 9Rheumatology, Hôpital Hautepierre, Strasbourg, France; 10Rheumatology, School of Medicine, National University of Athens, Greece; 11Rheumatology, Vedanta Institute of medical Sciences, Ahmedabad, India; 12Rheumatology, Kyoto First Red Cross Hospital, Kyoto, Japan; 13Rheumatology, Kaunas University Hospital, Kaunas, Lithuania; 14Rheumatology, Medisch Spectrum Twente, Enschede, Netherlands; 15Rheumatology, Serlandet Hospital, Kristiansand, Norway; 16Rheumatology, Poznan Rheumatology Center in Srem, Srem; 17Rheumatology, Military Institute of Medicine, Warsaw, Poland; 18Rheumatology, Rheumatology Institut, Niska Banja, Serbia; 19Rheumatology, Moscow Medical Academy, Moscow, Russian Federation; 20Rheumatology, Hospital General de Castellon, Castellon, Spain; 21Rheumatology, Uppsala University Hospital, Uppsala, Sweden; 22Rheumatology, Uppsala University Hospital, Genova, Italy; 23Medicine, Jyväskylä Central Hospital, Jyväskylä, Finland

Background: Both rheumatoid arthritis (RA) and fibromyalgia (FM) affect predominantly females; FM is common in female RA patients [1]. DAS28 is used in the guidance of therapy in individual RA patients. Recently it has been shown that DAS28 values are higher in patients with RA and concomitant FM (RAF) than in RA patients without FM [1].

Objectives: To study DAS28 score in the assessment of disease activity in RAF patients in a multinational cross sectional cohort of patients with RA.

Methods: The Quantitative Standard Monitoring of Patients with RA (QUEST-RA) database includes 7,568 patients, who receive usual care from rheumatologists in 83 sites in 30 countries. Female RA patients (5,625 patients, mean age 55 yr, mean disease duration 11yr) were included in this analysis. Females were chosen because most FM patients were female and to avoid the influence of gender in analysis of disease activity [2]. A clinical assessment including review of comorbidities such as FM was performed by rheumatologists. Disease activity was assessed according to DAS28 (0-9.4). DAS28 was calculated in patients in four swollen joint categories: 0, 1-4, 5-12, and 13-28.

Results: A total of 3.6% of the female RA patients had concomitant FM (n= 202), no difference was found in age and disease duration between RAF and RA patients. RAF vs. RA patients had higher values for all ACR core data set measures except for SJC and ESR. The mean DAS28 values were higher in each SJC category in RAF patients compared to RA patients although statistical significance was reached only in patients with no swollen joints (Table).

<table>
<thead>
<tr>
<th>SJC28</th>
<th>0</th>
<th>1–4</th>
<th>5–12</th>
<th>13–28</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (RA/RAF)</td>
<td>1562/70</td>
<td>1731/78</td>
<td>1352/37</td>
<td>520/8</td>
</tr>
<tr>
<td>RA patients Mean DAS28 (SD)</td>
<td>3.1 (1.3)</td>
<td>4.2 (1.2)</td>
<td>5.4 (1.2)</td>
<td>6.6 (1.1)</td>
</tr>
<tr>
<td>RAF patients Mean DAS28 (SD)</td>
<td>3.4 (1.3)</td>
<td>4.4 (1.1)</td>
<td>5.5 (1.2)</td>
<td>6.9 (0.8)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.045</td>
<td>0.12</td>
<td>0.36</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Conclusion: In female RA patients with concomitant FM DAS28 values tend to be constantly higher compared to female RA patients without FM. DAS28 should be used with caution in measurement of disease activity in RAF patients.

References:


Disclosure of Interest: Non declared.

Background: While cardiac autonomic dysfunction (CAD) is frequently found in patients with fibromyalgia (FM), there have been different views as to which tests should be used. The Ewing tests (heart rate responses to deep breathing, Valsalva maneuver, and orthostatic standing and blood pressure response to standing) are simple and standardized, but they require a bit of time, patience, practice, and patient cooperation. Spontaneous heart rate variability (HRV) does not require patient's undue attention and is thought to be superior in that they can detect CAD earlier and with greater reliability. However, this test requires expensive additional medical equipment and data analysis.

Objectives: We studied the modulation of autonomic nervous system by means of Ewing tests and HRV in FM patients. In addition, we evaluated whether HRV is superior to the Ewing tests in detecting CAD.

Methods: We studied 35 women with FM (median age, 42 years) and 25 age-matched healthy women. Each abnormal test to deep breathing, Valsalva maneuver, or orthostatic standing was counted as 1 point. A change in systolic blood pressure (ΔSBP) during standing of >10mmHg was graded with 1 point and a change of >20 mmHg received 2 points. A total score of 0 was regarded as no CAD (noCAD), a score of ≥2 as severe CAD (sCAD), and a score of 1 as mild CAD (mCAD). HRV was measured in two ways by statistical operations on R-R intervals (time-domain analysis) and spectral analysis of a series of successive R-R intervals (frequency-domain analysis).

Results: FM patients had significantly lower EI ratio, lower Valsalva ratio, and higher ΔSBP values than did healthy controls (p<0.05, p<0.05, p<0.01, respectively). In the frequency-domain analysis, VLF and LF were decreased in FM patients compared to controls (both p<0.05). Median group values for EI ratio, Valsalva ratio, ΔSBP, VLF, LF, and HF were: 1.29, 1.31, 1.30, 1.13 (p=0.001); 1.16, 1.28, 1.12, 1.07 (p<0.001); 1.07, 1.02, 1.05, 1.12, 1.19, 1.21, 1.16, 1.28, 1.12, 1.07 (p<0.001); 2.0, 2.5, 5.0, 7.0 (p<0.01); 442.2, 313.2, 343.8, 279.9 (p=0.161); 216.2, 124.7, 159.9, 79.3 (p=0.100); 246.1, 165.7, 204.4, 94.2 (p=0.094) for controls, noCAD, mCAD, and sCAD, respectively. Based on discriminant analysis of the Ewing tests, 54.4% of cases were classified correctly. The addition of HRV parameters did not improve reclassification.

Conclusion: FM patients had abnormal responses to two kinds of autonomic function tests. HRV did not detect CAD in FM patients better than classic autonomic testing.

Disclosure of Interest: None declared

Background: Alterations in hypothalamic-pituitary-adrenal (HPA) axis functioning have been commonly observed in subgroups of patients with fibromyalgia (FM). The cortisol awakening response has been shown to be particularly sensitive to psychological variables. In general, positive affective factors have been associated with lower morning cortisol levels, while negative affective factors have been associated with higher levels. However, the role of affective factors in cortisol awakening response has not been well studied in FM.

Objectives: To evaluate relationships between positive and negative affective factors and cortisol levels after awakening in patients with FM and healthy controls.

Methods: Composite scores based on data collected over three days were calculated for the initial awakening cortisol sample and for the second sample taken 60 minutes after awakening for 20 patients with FM and 26 healthy controls. The following variables were considered in light of their likely association with affect: Center for Epidemiological Studies–Depression Scale (CES-D); Short Form 36 Health Survey (SF-36) subscales: Mental Health, Role Emotional, and Social Functioning; and the anger and anxiety symptoms from the State-Trait Personality Inventory (STPI).

Results: We found that in the healthy controls, higher morning cortisol levels were related to the negative affective variables, depression (CESD; r = 0.372; p = 0.03) and anxiety (STPI; r = 0.41; p = 0.02), and inversely related to the positive affective variables SF-36 Role Emotional (r = -0.35; p = 0.05) and Mental Health (r = -0.41; p = 0.02) subscales. Conversely, in patients with FM, higher morning cortisol levels were not related to the negative affective variables. Instead, higher morning cortisol scores were related the positive affective variables including: SF-36 Role Emotional subscale (r = 0.49; p = 0.02), SF-36 Mental Health (r = 0.48; p = 0.02) and SF-36 Social Functioning (r = 0.45; p = 0.03). Overall, the relationships between cortisol and affective variables were most prominent at initial awakening and few of these relationships existed in composite cortisol scores evaluated later in the day.

Conclusion: Evaluation of affective variables in morning cortisol levels suggests a paradoxical relationship in FM. Unlike what was observed in the healthy controls, in FM positive affective factors were associated with higher morning cortisol levels, while negative affective factors were associated with lower morning cortisol levels. We hypothesize that because hypocortisolism is common in FM, perhaps the higher cortisol scores influenced by positive affective factors may be indicative of better HPA axis functioning. Future studies should explore this possibility.

Disclosure of Interest: None declared

Background: Fibromyalgia (FM) is a syndrome characterized by a central sensitization with an amplification of the pain perception. It is thought to occur because of the combination of interactions among neurotransmitters, such as neuropeptide Y (NPY), external stressors, behavioural constructs, hormones, the immune and sympathetic nervous systems. Moreover, FM-like symptoms appear in patients with malignancies or chronic hepatitis treated with cytokines, suggesting a possible role of cytokines in the pathogenesis of FM.

Objectives: The aim of the present study was to evaluate serum concentrations of cytokines, anti-polymer antibodies (APA) and NPY in two groups of patients, one with a diffused and one with a localized pain syndrome, respectively FM and Tension Type Headache (TTH). Then, these values were correlated with clinical parameters in FM.

Methods: The study population consisted of 51 consecutive female patients (mean age 49.6 yrs, range 23-75 yrs) with FM referring to our Unit of Rheumatology and 20 consecutive female patients (mean age 43.3 yrs, range 22-76 yrs) with TTH referring to the Headache Center. FM patients underwent careful historical interview, clinical and rheumatologic examination with tender points (TPs) count and clinimetric tests, such as FIQ, HAQ, VAS for pain, fatigue, stiffness, anxiety, depression, disease activity. FM severity was classified on the basis of the TPs count: the presence of 11-13 TPs was considered mild, 14–16 moderate and more than 16 severe. Serum concentrations of IL-1β, IL-1RA, IL-4, IL-6, IL-8, IL-10, IFN-γ and TNF-α were evaluated using commercially available multiplex bead-based sandwich immunoassay kits (Biorad CA, USA). Serum levels of IgG APA and NPY were measured by immunoenzymatic assays (Corgenix, Westminster, CO, USA and Phoenix Pharmaceuticals, Inc.USA).

Results: Interestingly enough, IL-1RA, IL-6, IL-10 and TNF-α were higher in serum of FM patients compared with TTH patients. This difference was statistically significative. Moreover, a significant correlation was demonstrated among concentrations of the pro-inflammatory cytokines IL-1, IL-6, IFN-γ, TNF-α in FM sera. A significant correlation between IL-10 and FIQ score was also observed (p = 0.046). Serum levels of APA and NPY were not statistically different between FM and TTH patients. APA were detected in 9 FM patients (17.6%). FM patients with high VAS pain score showed low APA serum levels (p = 0.029). No correlations were detectable between serum levels of NPY and clinical features or clinimetric scores in FM patients.

NPY, APA and cytokines levels did not show any correlation with mild, moderate or severe FM symptoms.

Conclusion: This is the first study that compares serum levels of cytokines, APA and NPY in a generalized and a localized pain syndrome and that shows a statistically significant difference in cytokines levels between FM and TTH. These results reinforce the hypothesis of a direct role of cytokines in the pathophysiology of FM. However, the serum levels of these cytokines seem not to correlate with the clinical features.

Disclosure of Interest: None declared.
A. Berger, G. Oster, T. Juday, M.H. Erder, S. Blum. Research, Policy Analysis Inc., Brookline; Health Outcomes, Forest Research Institute, Jersey City, United States

Background: Opioids are not typically recommended for the treatment of fibromyalgia (FM), due to their limited efficacy in this indication and risk of addiction and/or abuse. Little is known about the extent to which these agents are used in this patient population.

Objectives: To document patterns of use of opioids in FM patients in the US.

Methods: Using a large US health insurance database spanning a three-year period (1/1/2005 to 12/31/2007), we identified all patients with ≥1 medical encounters for FM (defined as ICD-9-CM code 729.1) in each of these three calendar years (FM patients'). We documented the percentage of patients receiving opioids (including both short- and long-acting formulations) as well as the number of prescriptions for—and therapy-days with—such agents in each of the three years. Prescriptions and therapy-days were annualized to account for differences in days of enrollment in each year.

Results: A total of 51,885 patients met all study entry criteria, of whom 37.2%, 38.9%, and 38.9% filled ≥1 prescriptions for opioids in 2005, 2006, and 2007, respectively. Most patients received short-acting opioids (36.4%, 37.9%, and 37.9%), although 7.2%, 8.6%, and 9.1% received long-acting formulations. The most commonly used short-acting opioids were hydrocodone (~24% annually), followed by oxycodone (~11% annually), and tramadol (~10%); the most commonly used long-acting opioids were oxycodone (~3%), fentanyl (~3%), and morphine (~2%). On an annualized basis, FM patients who received opioids averaged 8.0 (95% confidence interval = 7.9, 8.1) prescriptions for such therapy constituting 158.6 (155.6, 161.6) therapy-days in 2005; corresponding values were 8.5 (8.4, 8.7) and 178.9 (175.8, 182.1) for 2006 and 8.3 (8.2, 8.5) and 181.4 (178.2, 184.6) in 2007. FM patients who received opioids also often received other FM-related therapies, including antidepressants (used by ~63% of such patients annually), followed by sedatives/hypnotics (~33%), and antiepileptics and antidepressants (~28%).

Conclusion: Despite a lack of demonstrated efficacy in this disease and their potential for addiction and abuse, opioids are used by more than one-third of FM patients. Further research is needed to understand why the use of these agents in clinical practice is so high.

Disclosure of Interest: A. Berger, Forest Research Institute, Consultant G. Oster, Forest Research Institute, Consultant T. Juday, Forest Research Institute, Employee S. Blum, Forest Research Institute, Employee M.H. Erder, Forest Research Institute, Employee

Ann Rheum Dis 2009;68(Suppl3):691
Background: Among patients with Sjögren's syndrome (SjS), the prevalence of fatigue is in the range of 68–74%. As far as we know, despite its clinical relevance in SjS, only a few studies have examined the relationship of fatigue with other clinical variables. We therefore assessed the link among fatigue and anxiety, depression, the presence of an overlapping Fibromyalgia (FM), disease activity and the damage associated to SjS.

35 female patients (mean age 53 yrs; range 27-70 yrs) with primary SjS (diagnosis according to the Euro-American criteria) (1) (mean disease duration 11 yrs; range 3-31 yrs) attending the Sjögren's clinic, were consecutively enrolled. After obtaining informed consent, for each patient Sjögren's Syndrome Disease Damage Index (SSDDI) and the Sjögren's Syndrome Disease Activity Index (SSDAI) were calculated (2). Patients rated pain, fatigue and disease activity using a 100-mm Visual Analog Scale (VAS) and completed the HAQ, the Fibromyalgia Impact Questionnaire (FIQ). Furthermore, the Zung depression and anxiety scales were used to quantify aspects of mood disorders. Pressure pain threshold was determined at the 18 ACR tender points using an algometer (dolorimeter). A patient was deemed to have FM when fulfilling ACR classification criteria for the disease (3). Spearman Rank Correlation Test, Principal component analysis (PCA) and Principal Components Analysis for Categorical Data (CATPCA) were used for statistical analysis.

30/35 patients (85,7%) felt unduly tired with a mean VAS for fatigue 68,3 (range 5-100), the remaining 5/35 (14,3%) denied to have fatigue; 30/35 (85,7%) suffered with pain in more than one area of the body on most days with a mean VAS for pain 55,7 (range 5-100) while 5/35 (14,3%) denied generalized pain. Seven patients satisfyed ACR criteria for FM representing 20% of all the cohort and 23% of SjS patients with fatigue. No differences were found in disease duration, SSDDI, SSDAI, Zung depression and anxiety scales results among SjS patient with or without FM.

In the whole group, VAS fatigue correlated with HAQ, ZSAS, ZSDS, and VAS pain, but not with age, disease duration, presence and severity of arthritis, SSDDI, SSDAI. FM can contribute to, but do not entirely account for, fatigue in patients with primary SjS.

References:

Disclosure of Interest: None declared.
Background: Fibromyalgia (FM) is a chronic disorder characterized by persistent and widespread pain, fatigue, and other symptoms. FM is associated with significant health care costs related to medications, physician office visits, and lost productivity, due to absenteeism and disability. This study examines costs associated with FM in France and Germany.

Methods: This cross-sectional, observational study included 299 FM subjects recruited from 33 community-based physician offices in France and Germany. Subjects completed questions about their pain, health-related quality-of-life, productivity, and out-of-pocket expenses related to FM; site staff recorded subject demographic, treatment, and medical resource use information based on a review of medical records. FM severity was defined using subjects' FIQ total scores. Annual costs from a societal perspective were calculated in 2008 Euros and included direct medical (e.g., physician office visits, medications), direct non-medical (e.g., home healthcare services), and indirect non-medical (e.g., missed days of work and lost productivity) costs.

Results: Subjects were reported to have a mean (SD) of 2.9 (1.9) physician office visits in France and 4.9 (3.2) visits in Germany over the past 3 months. French subjects reported higher use of analgesics (59% of patients) and lower use of anti-inflammatories (39% of patients) compared to German subjects (34% and 67% of patients, respectively). Subjects employed full- or part-time reported missing a mean (SD) of 2.7 (6.0) days of work to FM in France and 2.1 (3.8) days of work due to FM in Germany over the last four weeks (corresponding to 32.4 and 25.2 days of work missed due to FM per year in France and Germany, respectively). In France, total costs were €7,900 (direct medical = €808; direct non-medical = €103; indirect = €6,990). In Germany, total costs were €7,256 (direct medical = €1,513, direct non-medical = €252, indirect costs = €5,491). A trend of higher total costs was seen as FM severity increased; however, the results were significant (p=0.0002) only for Germany.

Conclusion: FM imposes a significant economic burden on society. Consistent with other studies, FM subjects were found to have substantial direct and indirect costs associated with FM, and these costs increase as FM severity increases. While German subjects have higher medical resource costs and French subjects have higher lost productivity costs, overall FM costs are similar between France and Germany.

 Disclosure of Interest: A.Winkelmann, Pfizer, Grant Research Support
S.Perrot, Pfizer, Grant Research Support
K.Ryan, Pfizer, Consultant
C.Schaefer, Pfizer, Consultant
X.Xu, Pfizer Consultant
A.Chandran, Pfizer, Employee
A.Sadosky, Pfizer, Employee
G.Zlateva, Pfizer, Employee

Ann Rheum Dis 2009;68(Suppl3):687
Background: The ACR 1990 criteria for fibromyalgia (FM) include both widespread pain and tenderness to blunt pressure. The relationship of tenderness to pathophysiology of FM is not known. Milnacipran is a dual noradrenaline (NA) and serotonin (5-HT) reuptake inhibitor. It has shown efficacy in treating FM in several recent controlled trials.

Objectives: To examine the impact of 12-weeks of treatment with milnacipran versus placebo on the pressure pain, and to image via functional magnetic resonance (fMRI).

Methods: Ninety two right handed FM female patients (UK, Germany and Sweden) participated in a 13-week, double-blind, placebo controlled, randomized trial assessing the effect of milnacipran 100 mg bid or placebo on brain activity measured by fMRI before and after treatment. Before inclusion, all patients reported a spontaneous baseline pain level ≥40 (of 100) on a VAS. Pressure was applied to the thumbnail using a handle giving multiple pressures of various intensities at Day–1 (baseline) and Week 12 (study end). VAS ratings of pain intensity were recorded and stimulus-response curves calculated. The amount of applied pressure that represented each patient's VAS 50mm, VAS50, was used to produce a controlled painful stimulus during the fMRI session. During fMRI, an event-related paradigm of pressures to the thumb was used. A weak, non-painful pressure was also used as a control stimulus. Brain activity during the administration of non-painful pressures was subtracted from the activity during the painful stimulus.

Results: The milnacipran group exhibited hyperactivities in regions involved in the inhibition of pain such as the caudatus nucleus, anterior insula and the amygdale compared to baseline. The placebo group exhibited few regions where there was a change in neural activity as compared to baseline. There was one significant region where milnacipran led to significant higher activity after treatment, i.e. the precuneus and posterior cingulum (t=3.73, p<.05).

Conclusion: Milnacipran alters activity evoked by painful pressure in brain regions known to be involved with pain modulation. The main extraparietal connections of the post cingulum/precuneus are with the frontal lobes. The posterior cingulum/precuneus region has no direct connections to the primary sensory cortices, which suggests that the effect of milnacipran probably is due to modification of higher level pain processing functions rather than a modification of the direct processing of external stimuli.

Disclosure of Interest: M.Ingvar, Pierre Fabre, Honorarium
F. Petzke, Pierre Fabre, Honorarium
H. Markus, Pierre Fabre, Honorarium
K. Jensen, Pierre Fabre, Honorarium
E. Kosek, Pierre Fabre, Honorarium
E. Choy, Pierre Fabre, Honorarium
S.C.R. Williams, Pierre Fabre, Honorarium
R. Gracey, Pierre Fabre, Honorarium
M. Groc, O. Vitton, Y. Mainguy, Pierre Fabre employees
S. Rao, CypressBioscience employee

Ann Rheum Dis 2009;68(Suppl3):691
[AB0556] SOCIODEMOGRAPHIC AND CLINICAL VARIABLES RELATED TO THE LACK OF RESPONSE TO MULTIDISCIPLINARY TREATMENT PROGRAM IN PATIENTS WITH FIBROMYALGIA

A. Conesa, A. Collado, X. Torres, A. Arias, M. Farres, J. Muñoz. Fibromyalgia Unit, Department of Rheumatology, Hospital Clinic, Barcelona, Spain

Ann Rheum Dis 2009;68(Suppl3):758
SP0077] GLUTAMATE LEVELS IN THE INSULA AND PAIN PERCEPTION IN FIBROMYALGIA

R.E. Harris. Department of Anesthesiology, University of Michigan, Ann Arbor, United States

Objective: Central pain augmentation resulting from enhanced excitatory and/or decreased inhibitory neurotransmission is a proposed mechanism underlying the pathophysiology of functional pain syndromes such as fibromyalgia (FM). Multiple functional magnetic resonance imaging (fMRI) studies implicate the insula as a region of heightened neuronal activity in this condition. Since glutamate (Glu) is a major cortical excitatory neurotransmitter that functions in pain neurotransmission, we hypothesized that increased levels of insular Glu would be present in FM patients and that the concentration of this molecule would be correlated with pain report. We recently have reported that reductions of insular Glu in FM patients are correlated with decreased experimental and clinical pain report (REHarris et al. Arthritis and Rheumatism, 2008).

Methods: 19 FM patients and 14 age- and sex-matched pain free controls underwent pressure pain testing and a proton magnetic resonance spectroscopy (H-MRS) session wherein the right anterior and right posterior insula were examined at rest.

Results: FM patients had significantly higher levels of Glu (mean(SD): FM 8.09(0.72); HC 6.86(1.29); p=0.009) and combined glutamate and glutamine (e.g. Glx; mean(SD): FM 12.38(0.94); HC 10.59(1.48); p=0.001) within the right posterior insula as compared to controls. No differences were detected in any of the other major metabolites within this region (all p>0.05) and no group differences were detected for any metabolite within the right anterior insula (all p>0.10). Within the right posterior insula, higher levels of Glu and Glx were associated with lower pressure pain thresholds across both groups (Glu: r=-0.43; p=0.012; Glx: r=-0.50; p=0.003).

Conclusion: Enhanced glutamatergic neurotransmission resulting from higher concentrations of Glu within the posterior insula may play a role in the pathophysiology of FM and other central pain augmentation syndromes.

References:


Disclosure of Interest: R.E. Harris Pfizer, consultant

HOW DOES FIBROMYALGIA IMPACT PATIENTS? RESULTS FROM A EUROPEAN CROSS-SECTIONAL STUDY

S. Perrot¹, A. Winkelmann², X. Xu³, C. Schaefer³, K. Ryan⁴, E. Dukes⁴, A. Chandran⁴, A. Sadosky⁴, G. Zlateva⁴. ¹Service de Médecine Interne et Thérapeutique, Hôtel Dieu Hospital, Université Paris Descartes, Paris, France; ²Department of Physical Medicine and Rehabilitation, University Hospital Munich, Munich, Germany; ³Covance Market Access Services, Covance, Gaithersburg; ⁴Global Health Economics, Pfizer, New York, United States

Ann Rheum Dis 2009;68(Suppl3):758
[AB0562] HEALTH-RELATED QUALITY OF LIFE IN FIBROMYALGIA PATIENTS: A COMPARISON WITH RHEUMATOID ARTHRITIS PATIENTS AND HEALTHY CONTROLS USING THE SF-36 HEALTH SURVEY

F. Salaffi¹, F. Atzeni², R. Girolimetti¹, P. Sarzi-Puttini², S. Gasparini¹, W. Grassi¹. ¹Department of Rheumatology, Polytechnic University of Marche Medical School, Ancona; ²Rheumatology Unit, L. Sacco University Hospital, Milan, Italy

Ann Rheum Dis 2009;68(Suppl3):759
[AB0569] GH-IGF1 AXIS IN SEVERE FIBROMYALGIA PATIENTS: SCREENING DATA FROM THE CT27560 TRIAL

M. Gonzalez¹, G. Cuatrecasas², G. Sesmilo³, B. Yoldi¹, M. Ramentol¹, R. Huguet¹, J. Cabrera⁴, C. Alegre¹. ¹Rheumatology, Institut Universitari Dexeus; ²Endocrinology, Centre Mèdic Tecknon; ³Endocrinology, Institut Universitari Dexeus; ⁴Industry, Merck Pharma&Q, Barcelona, Spain

Ann Rheum Dis 2009;68(Suppl3):759
FIBROMYALGIA: RUSSIAN RHEUMATOLOGISTS’ KNOWLEDGE

E. Nasonov¹, D. Soldatov², K. Lelay³, C. Taieb³

¹Rheumatology Institute, PFSA; ²Medical Dpt, Pierre Fabre Laboratories, Moscow, Russian Federation; ³Public health and Quality of life, PFSA, Boulogne Cedex, France

Ann Rheum Dis 2009;68(Suppl3):758
J. Asueta-Lorente¹, D. Tordeurs², P. Janne³, E. Baruffol³, C. Reynaert⁴, M. Léon¹. ¹Rheumatology, CHU Ambroise Paré, Mons; ²Psychologie, Cliniques universitaires UCL Mont-Godinne, Yvoir; ³Psychologie, Université catholique de Louvain, Louvain-la-Neuve; ⁴psychosomatique, Cliniques universitaires UCL Mont-Godinne, Yvoir, Belgium

Ann Rheum Dis 2009;68(Suppl3):759
FIBROMYALGIA IN PATIENTS WITH RHEUMATOID ARTHRITIS; DIAGNOSTIC UTILITY OF AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA AND REGIONAL PAIN SCALE

G. Can, O. Soysal, D. Solmaz, O. Binicier, F. Onen, N. Akkoc, S. Akar. Rheumatology, Dokuz Eylül University Faculty of Medicine, Izmir, Turkey

Ann Rheum Dis 2009;68(Suppl3):759
FIBROMYALGIA IN BEHCETS DISEASE IS ASSOCIATED WITH ANXIETY, DEPRESSION, SLEEP QUALITY AND QUALITY OF LIFE

M. Toprak, I. Tekeoglu, O. Hýz. Physical Medicine and Rehabilitation and Rheumatology, Faculty of Medicine, Van, Turkey

Background: Fibromyalgia (FM) is common in autoimmune diseases (1), and is the source of many of the symptoms and much of the disability in Behçets disease (BD). Psychiatric symptoms and quality of life measures are important outcome factors in BD (2). Studies on the assessment of FM, psychiatric symptoms and quality of life BD are limited (3).

Objectives: We aimed to determine the prevalence of FM in BD and to evaluate their association with anxiety, depression, sleep quality and quality of life.

Methods: 97 people were selected from consecutive patients who applied to BD outpatient clinics of a university hospital and 95 healthy subjects with similar sociodemographical status (age, sex, educational level and marital status) were recruited as controls. The patients and controls were assessed with Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Pittsburgh Sleep Quality Index (PSQI) and Quality of Life (SF36 and WHOQOL Bref).

Results: 19 (%20.1) of the BD patients were diagnosed with FM according to the criteria of American College of Rheumatology (4). All patients with FM were female. BDI and BAI scores were significantly higher in BD group compared to controls. No significant difference was found between PSQI scores. BD patients had significantly lower scores in domains of SF36 except vitality, mental health, physical and psychological subscale scores of WHOQOL Bref. While BDI and PSQI scores were significantly higher in BD patients with FM, physical functioning, role physical, bodily pain, vitality, social functioning, role emotional and mental health of SF36 and psychological WHOQOL Bref scores were significantly lower. Overall, a significantly negative corelation was found in all SF36, WHOQOL Bref subscale scores and BDI, BAI, PSQI scores in BD patients.

Conclusion: In this study FM was very common among BD patients and was associated with the presence of anxiety, depression, sleep quality and quality of life. Therefore BD patients with FM may benefit from psychological evaluation as part of their treatment.

References:


Disclosure of Interest: none declared

Ann Rheum Dis 2009;68(Suppl3):598
FIBROMYALGIA FATIGUE– DEVELOPMENT OF A CONCEPTUAL MODEL BASED ON QUALITATIVE PATIENT INTERVIEWS

1Seattle Rheumatology Associates, and University of Washington School of Medicine, Seattle, United States; 2Mapi Values, Bollington, United Kingdom; 3University of Michigan, Ann Arbor, United States; 4Frederiksberg Hospital, Copenhagen University Hospital and Aalborg University, Denmark; 5Pfizer Outcomes Research, Sandwich, United Kingdom

Ann Rheum Dis 2009;68(Suppl3):759
AB0564] FEATURES OF CORRELATIONS OF PAIN FACTOR AND EMOTIONAL STATUS IN PATIENTS SUFFERING FROM PRIMARY FIBROMYALGIA

G.P. Suleimanova¹, R.A. Grekhoff¹, S.A. Kharchenko¹, A.B. Zborovsky², I.A. Zborovskaya². ¹Clinical Psychology Laboratory; ²Clinical Department, Research Institute for clinical and experimental rheumatology, Volgograd, Russian Federation

Ann Rheum Dis 2009;68(Suppl3):759
EQ-5D AND SF-36 QUALITY OF LIFE MEASURES IN SYSTEMIC LUPUS ERYTHEMATOSUS: COMPARISONS WITH RA, NON-INFLAMMATORY RHEUMATIC DISORDERS (NIRD), AND FIBROMYALGIA (FM)

F. Wolfe1, K. Michaud2, T. Li3, R.S. Katz4. 1Rheumatology, National Data Bank for Rheumatic Diseases, Wichita; 2Rheumatology, University of Nebraska Medical Center, Omaha; 3Outcomes Research, Bristol-Myers Squibb, Princeton; 4Rheumatology, Rush University Medical Center, Chicago, United States

Background: The SF-36 provides numerical measurement of patient health, but does not include preferences for health states and cannot be used in cost-effectiveness analyses. By contrast the EQ-5D is based on preferences and produces utility scores. However, EQ-5D has not been used before in SLE.

Objectives: To describe the comparative HRQOL of the four groups of rheumatic disease patients according to SF-36 and EQ-5D - EQ-5D VAS results, examine predictors of HRQOL in SLE, and characterize results in term of patients' satisfaction with health.

Methods: We studied 1,316 patients with SLE, 13,722 with RA, 3,623 with NIRD, and 2,733 with FM. We determined SLE damage by the newly developed Lupus Damage Index Questionnaire (LDIQ), a self-report version of the ACR/Systemic Lupus International Collaborating Clinics (SLICC) Damage Index (SDI).

Results: The mean EQ-5D, PCS and MCS scores were 0.72, 36.3, and 44.3 in SLE. There was essentially no difference among EQ-5D and PCS scores for patients with SLE, RA, or NIRD. MCS was lower in SLE compared with RA and NIRD (44.3, 49.1, 50.8). All scores were much more abnormal in FM (0.61, 31.9, 41.9). Within SF-36 domains, function was better, but general health, vitality, social function, emotional role, and mental health were more impaired in SLE compared with RA and NIRD. In SLE, QOL was predicted by damage (Figure 1), comorbidity, household income, education, and age. 15% of patients with SLE were very satisfied with their health, and their QOL scores (0.84, 45.4, 50.1) were the similar to those as found in the population for EQ-5D and MCS, but slightly reduced for PCS.

Conclusion: HRQOL in SLE, RA, and NIRD is similar with respect to SF-36 PCS and EQ-5D. SLE patients have the lowest MCS scores of the 3 disorders. Patients with fibromyalgia have the lowest HRQOL scores, regardless of measure. HRQOL in SLE is predicted by damage, comorbidity, age, household income, and educational attainment. About 47% of SLE patients are somewhat (22.1%) or very satisfied (15.1%) with their health.

Disclosure of Interest: None declared

[AB0580] EFFICACY OF PREGABALIN FOR PATIENTS WITH FIBROMYALGIA IN EUROPE, THE US, AND OTHER GEOGRAPHIC REGIONS


Ann Rheum Dis 2009;68(Suppl3):760
LONG-TERM MAINTENANCE OF IMPROVEMENTS IN FUNCTION, SLEEP, AND FATIGUE IN FIBROMYALGIA PATIENTS WITH PREGABALIN TREATMENT


Ann Rheum Dis 2009;68(Suppl3):759
PREGABALIN-TREATED PATIENTS DEMONSTRATE CLINICALLY RELEVANT IMPROVEMENT ON COMPOSITE RESPONDER ANALYSES


Background: Fibromyalgia is a multi-dimensional disease that is marked by chronic widespread pain, as well as fatigue, sleep disturbance, and loss of function. Treatment with pregabalin has shown a clinically meaningful benefit in fibromyalgia across multiple measures of pain, sleep, and function.

Objectives: To examine the effect of pregabalin on multiple symptom domains of fibromyalgia through composite responder analyses.

Methods: Data from 3 randomized, placebo controlled, fixed-dose studies of pregabalin were pooled. Two composite responder analyses were performed using clinically meaningful changes as identifiers of response. Specifically, the proportions of patients responding on any or all of the domains of pain (≥30% reduction in mean pain score), Fibromyalgia Impact Questionnaire (FIQ) total score (≥16 point reduction), and Medical Outcomes Study – Sleep Scale (MOS-SS) sleep disturbance (≥15.8 point reduction), which are equivalent to 2-category changes in Patient Global Impression of Change (PGIC), were assessed. Clinically important differences for each of the FIQ subscales equivalent to a 2-category change in PGIC, were established, and the proportion of patients responding at these levels in at least 5 of 10 FIQ subscales was determined.

Results: Composite responder analyses showed more frequent achievement of improvements in all symptom domains with pregabalin at all doses than placebo (p<0.05). At doses of 450 mg/day, 23% of pregabalin-treated patients vs. 15% of placebo-treated patients showed improvement in all symptom domains (pain, sleep, and function) (p<0.0008). Significantly more pregabalin-treated patients than placebo-treated patients responded on at least one domain, with ≥66% of patients treated with pregabalin vs. 52% of placebo-treated patients responding (p<0.0001 for all doses). The responder analysis of patients with improvement in at least 5 of the 10 subscales of the FIQ showed significantly more pregabalin-treated patients at each dose level compared to placebo had a clinically meaningful improvement, with 43% of those treated with pregabalin 450 mg/day responding compared to 33% on placebo. FIQ subscale responders showed similar levels of response across all 10 FIQ subscales and treatment groups. The most commonly reported adverse events in these trials were dizziness and somnolence.

Conclusion: Pregabalin-treated patients as compared to placebo-treated patients demonstrated clinically meaningful response on multiple symptom domains that are important to fibromyalgia patients.

Disclosure of Interest: Zeiher B, Pfizer employee

Pauer L, Pfizer employee
Szczypa P, Pfizer employee
Atkinson G, Pfizer employee
Murphy TK, Pfizer employee
Zlateva G, Pfizer employee

TEN YEARS EXPERIENCE IN A FIBROMYALGIA OUT-PATIENT CLINIC: IS THERE A HAPPY ENDING?

B. Yanik¹, D. Gokmen², U. Sarp³, Y. Kurtais Aytur³, S. Ergin³. ¹Physical Medicine and Rehabilitation, Fatih University Faculty of Medicine; ²Biostatistics; ³Physical Medicine and Rehabilitation, Ankara University Faculty of Medicine, Ankara, Turkey

Ann Rheum Dis 2009;68(Suppl3):760
AB0577] EFFECTIVENESS OF DIFFERENT MODALITIES TO PATIENTS WITH FIBROMYALGIA (FM)

S. Patru, A.C. Bighea, R. Popescu, A.M. Bumbea. Physical Medicine and Rehabilitation, University of Medicine and Pharmacy, Craiova, Romania

Ann Rheum Dis 2009;68(Suppl3):759
EFFECT OF THE COMBINED USE OF TRAMADOL AND MILNACIPRAN ON THE PAIN THRESHOLD IN FIBROMYALGIA ANIMAL MODEL

S. Kim¹, S. Kim², S. Kim³. ¹Internal Medicine, Dongguk Univ. Gyeongju Hospital, Gyeongju; ²Internal Medicine, Catholic University of Daegu School of Medicine; ³Internal Medicine, Keimyung University School of Medicine, Daegu, South Korea

Ann Rheum Dis 2009;68(Suppl3):759
EFFECT OF MILNACIPRAN ON BODY WEIGHT IN PATIENTS WITH FIBROMYALGIA: A POOLED ANALYSIS OF 2 RANDOMIZED, PLACEBO-CONTROLLED TRIALS

D.J. Clauw1, L.M. Arnold2, R.H. Palmer3, M.R. Hufford4, R. Zablocki5, W. Chen6. 1Rheumatology, University of Michigan, Ann Arbor; 2Department of Psychiatry, University of Cincinnati College of Medicine, Cincinnati; 3Clinical Development, Forest Research Institute, Jersey City; 4Clinical Development; 5Biostatistics, Cypress Bioscience, Inc., San Diego; 6Biostatistics, Forest Research Institute, Jersey City, United States

Ann Rheum Dis 2009;68(Suppl3):759
POOLED ANALYSIS OF 3 OPEN-LABEL EXTENSION STUDIES ON THE LONG-TERM SAFETY AND TOLERABILITY OF PREGABALIN TREATMENT IN PATIENTS WITH FIBROMYALGIA

T.K. Murphy¹, P. Szczypa², L. Whelan³, G. Atkinson³, L. Pauer⁴, B. Zeiher⁴. ¹Pfizer Global Pharmaceuticals, Pfizer Inc, New York, United States; ²Pfizer Global Pharmaceuticals, Pfizer Inc, Walton Oaks; ³Pfizer Global Research & Development, Pfizer Inc, Sandwich, United Kingdom; ⁴Pfizer Global Research & Development, Pfizer Inc, New London, United States

Ann Rheum Dis 2009;68(Suppl3):760
CONNECTIVE TISSUE DISEASE-ASSOCIATED SYMPTOMS IN FIBROMYALGIA PATIENTS

Ö. N. Pamuk¹, E.G. Ümit², S. Dönmez¹. ¹Rheumatology; ²Internal Medicine, Trakya University Medical Faculty, Edirne, Turkey

Ann Rheum Dis 2009;68(Suppl3):759
COGNITIVE EVALUATION IN PATIENTS WITH FIBROMYALGIA, CORRELATION WITH DEPRESSION SYMPTOMS AND SEVERITY OF THE DISEASE


Ann Rheum Dis 2009;68(Suppl3):759
J. Rivera¹, J. Esteve-Vives², M. Vallejo³. ¹Unidad de Reumatología, IPR. Hospital Universitario Gregorio Marañón, Madrid; ²Sección de Reumatología, Hospital Gral. Universitari d’Alacant, Alicante; ³Departamento de Psicología de la Personalidad, Evaluación y Tratamientos Psicológicos, UNED, Madrid, Spain

Ann Rheum Dis 2009;68(Suppl3):759
H. Kim¹, B. Park², S. Kim³. ¹Division of Rheumatology, Department of Internal Medicine, The Chosun University Hospital, Gwangju; ²Division of Rheumatology, Department of Internal Medicine, Sun general hospital, Daejeon; ³Division of Rheumatology, Department of Internal Medicine, Dongsan Medical Center, Daegu, South Korea

Ann Rheum Dis 2009;68(Suppl3):759
A.P. Marques, A. Assumpção, A. Sousa, J.F. Sauer, P.C. Mango. Physical Therapy, Speech and Occupational Therapy Department, University of São Paulo, São Paulo, Brazil

Ann Rheum Dis 2009;68(Suppl3):759
[AB0558] IS SEXUAL ABUSE DURING INFANCY A SERIOUS CLINICAL FACTOR IN PATIENTS WITH FIBROMYALGIA (FM)?

B. Casanueva¹, J.L. Peña-Sagredo², A. Perez-Martín³, R. Sanchez-Villar⁴, B. Rodero-Fernandez¹, M.A. Gonzalez-Gay⁴. ¹Rheumatology, Specialist Clinic of Cantabria; ²Rheumatology, HUMV; ³Rheumatology, Specialist Clinic Cantabria, Santander; ⁴Rheumatology, Hospital Xeral-Calde, Lugo, Spain

Ann Rheum Dis 2009;68(Suppl3):758
Background: Fatigue is an important symptom. OMERACT and EULAR/ACR recommend including fatigue in every RA clinical trial. However, research studies have suggested that fatigue is unrelated to RA inflammation (Wolfe 1996, Pollard 2006). The DAS-28 measure of RA activity offers an opportunity to clarify the role of fatigue.

Objectives: To categorize the inflammatory content of RA measures, and compare and analyze levels of fatigue in RA, osteoarthritis (OA), and fibromyalgia (FM).

Methods: We studied fatigue (VAS 0-10 scale) and DAS-28 in 8,315 observations in 3342 RA patients from rheumatology practices and in 41,847 patients with RA, OA, and FM where DAS-28 scores were not obtained.

Results: DAS-28 and clinical measures were divided into two groups in factor analysis. Patient variables (loadings >0.714): pain, HAQ, fatigue, and global; and physician-inflammation variables (loadings >0.668): joint swelling, joint tenderness, MD global activity. Fatigue was correlated with DAS measures as follows: swollen joints 0.067, tender joints 0.241, ESR 0.095, patient global 0.503, DAS-28 0.340. We used hierarchal regression to examine the relative contribution of DAS components to fatigue scores. Swollen joints, tender joints, and ESR resulted in a model R-square of 0.088. The addition of patient global raised the R-square to 0.451. Thus, physician-inflammatory components contributed only 8.8% to fatigue variance compared with 44.7% for patient measures. Using a fixed-effect longitudinal regression model, we determined that a 1-unit change in the DAS-28 resulted in a 0.54 (95% CI 0.45, 0.63) change in fatigue.

The mean fatigue score was 4.9 (SD 3.0). In clinical settings where DAS-28 was collected, fatigue scores in RA were -0.20 units lower than in OA (p=0.404); in all clinical centers regardless of DAS availability the scores were -0.03 units lower (p=0.874), and in patients followed in survey research RA scores were 0.22 unit higher (p<0.001). Scores in FM were substantially increased (Figure 1).

Conclusion: There is a weak association between inflammatory measures of RA disease activity and fatigue. Fatigue levels are similar in RA and OA. The complaint of fatigue, its impact on patients, and its response to therapy is not unique to RA.

References:


Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):149
[AB0570-AHP] SOCIAL SUPPORT AND LIFE SATISFACTION AMONG FIBROMYALGIA WOMEN

M. Kukkurainen¹, H. Kautiainen¹, M. Mikkelsson², H. Kyngäs³. ¹Research, Rheumatism Foundation, Heinola; ²Rehabilitation Center, Päijät-Häme Intermunicipal Federation for Social Services and Health Care, Lahti; ³Department of Nursing and Health Administration, University of Oulu, Oulu, Finland

Ann Rheum Dis 2009;68(Suppl3):759
[AB0555] ASSOCIATION RESTLESS LEGS SYNDROME AND FIBROMYALGIA: CONTROLLED STUDY OF 102 PATIENTS

A. Simon, C. Dufauret-Lombard, C. Bonnet, P. Vergne-Salle, P. Bertin, R. Trèves. Service de Rhumatologie et Thérapeutique, CHRU Dupuytren, LIMOGES, France

Ann Rheum Dis 2009;68(Suppl3):758
AB0581] CORRELATION OF FATIGUE AND CLINICAL AND QUALITY OF LIFE PARAMETERS IN FIBROMYALGIA SYNDROME

Y. Turan, B. Beydag Odabasi, O.F. Sendur. Physical Medicine and Rehabilitation, Adnan Menderes University School of Medicine, Aydin, Turkey

Ann Rheum Dis 2009;68(Suppl3):760
Background: Vitamin D deficiency is a common problem in Middle Eastern as well as Bangladeshi, Indian and Pakistani populations. Vitamin D deficiency is highly prevalent in Emirati women and appears largely attributable to insufficient sunlight exposure. It is associated with increased bone turnover. Fibromyalgia as well as non specific muscle diseases are associated with Vitamin D deficiency. However, this relationship between vitamin D deficiency and muscle pain or fibromyalgia is more consistent among people of African, indo-pakistani, or aboriginal origins, as well as veiled populations rather than a caucasian population.

Objectives: The aim of our study was to determine the prevalence of Vitamin D deficiency (<20 ng/dl) among patients with fibromyalgia or muscle pain and tenderness in a musculoskeletal clinic in the Middle East.

Methods: Consecutive patients who were diagnosed with fibromyalgia and/or non-specific musculoskeletal pain (ICD-9 729.1) were screened for Vitamin D deficiency as well hypothyroidism. Data on age, race, style of dress and other diagnoses was also collected. Vitamin D assay was done by Roche assay (Electric Chemiluminescent immunoassay). All patients had a baseline thyroid stimulating hormone (TSH), calcium and phosphorus level. Patients were seen at follow-up 1 montha for treatment with Vitamin D was given. Improvement was only assessed by a simple questionnaire: Muscle pain 1) Gone 2) Much better 3) slightly better 4) Same.

Results: 139 consecutive patients with the diagnosis of fibromyalgia or muscle pain were seen in 2007. Their average age was 40 years ± 11.5; 95% were female. 69 (49%) were Arab, of whom 92% were veiled; 43 (30%) Indian of whom 11% were veiled, 80% wore long pants and/or full sleeved clothes and 9% wore western clothes; 23 (16%) were Caucasian and all wore western attire. 103 patients (74%) of these patients had a low vitamin D level. Vitamin D deficiency was most common among Arab patients (86%) and Indo-Pakistani (87%); and least common among the Caucasians (8%). Vitamin D deficiency was equally prevalent among veiled and non-veiled Patients.

The patients who had severe Vitamin D deficiency (< 15 ng/dl) were treated with either high dose Vitamin D3 injections (600,000 IU Im single dose). 50 patients received the high dose of Vitamin D and follow-up was done 1 month later. 90% of the patients had improved clinically (45 out of 50) with significantly decreased or absent myalgia (1 or 2 on questionnaire). All patients had normal calcium levels and normal vitamin D levels at followup. Patients with levels between 16- 20 ng/dl were treated with Alpha calcidiol 1 mg daily with follow-up in 1 month. However, out of 53 patients treated with oral therapy only 10 retuned for follow-up and these had improved clinically (response 1 or 2) with normal Vitamin D levels. However, our Indo-Pakistani patients who were mostly non veiled, wore conservative long sleeved clothing and did not spend time in the sun.

Conclusion: A diagnosis of Fibromyalgia or non-specific muscle pains in Arab or Indo-Pakistani women could mean vitamin D deficiency. This was equally true of veiled and non-veiled, but conservatively dressed populations. Prompt treatment with high dose Vitamin D could lead to resolution of all symptoms.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):689
Chronic widespread pain (CWP) is reported to have a high prevalence in different European countries (1), and musculo-skeletal pain is particularly prominent. Pain leads for the individual to disability, and CWP has significant economic implications for society (2). There are indications that CWP adds an increasing part to the cost of public health care (3). The initial pain symptoms are often localized to the muscles, appearing as activation of specific trigger points, possibly by changing the biochemical environment (4). What particularly triggers the spread of this pain situation into hitherto normal functioning areas is yet to be discovered. However, evidence points towards a significant role of the central nervous system with central sensitization as the suggested underlying mechanism (5).

FMS, a subgroup of CWP, has been a great challenge during the last decades, not only due to the high prevalence in the population, but also diagnostically. New pathological and physiological knowledge about pain does give hope of a better diagnosis and may enlighten the possible association between FMS and increased mortality (6).

FMS is so far characterized by chronic widespread pain - a syndrome where the patient suffers from musculo-skeletal pain, impaired physical function, and psychological distress. The diagnosis is defined by the ACR-criteria. The core diagnostic feature of FMS is a reduced threshold for pain sensation in muscle, generally identified by an increased sensitivity to pressure with hyperalgesia, and sometimes allodynia. Usually this feature is tested clinically by applying a pressure of about 4 kg via the examiner's fingertip. These findings of muscle hyperalgesia are confined also when using standardized and observer independent measures of deep tissue sensitivity (7).

Many diseases appear initially as localized pain, and in some cases they develop into generalized pain, which persists throughout life. Localised pain may thus increase and little by little involve the whole body. This phenomenon is seen in several medical specialties. Therefore it is important, not only for rheumatologists, but also for other specialists, particularly surgeons and general practitioners, to have knowledge of how to diagnose FMS. Importantly, the FMS criteria specifically state that FM is not a diagnosis of exclusion. Thus a finding of abnormal serology or radiographic changes does not rule out a diagnosis of FM. This is an important point, as FM is a common companion to rheumatic disorders such as rheumatoid arthritis, SLE and Sjogren’s syndrome. The case history of any patient with a complaint of musculo-skeletal pain must include either questioning about symptoms from other parts of the body, or, if possible, a pain drawing. Even CWP has fluctuations, and this will show up as variation in pain over time in different areas, and the area, which is the main problem now may shift to another area with time.

The most obvious rheumatological diseases to be distinguished from FMS, however, are degenerative and inflammatory joint diseases, which are all associated with pain. With a sufficiently large number of joints involved, this may in fact give rise to wide-spread pain of the same nature as fibromyalgia. A specific diagnosis is important in order to give the correct and effective treatment.

The main objective for this lecture is therefore to give clinically usable tools to differentiate and select patients with FMS diagnostically. To give a patient a main diagnosis as early as possible is of great importance and urgency and must be recommended.

References:


**Disclosure of Interest:** None declared

Background: Fibromyalgia syndrome (FMS) characterized by chronic generalized pain and related symptoms is a mysterious condition with uncertain pathogenesis. In spite of the skepticism of some, it seems that the medical science community has accepted FMS as a valid, unique clinical diagnosis and the main theory explaining it (the central sensitization model) may relate to many chronic pain states. Chronic generalized pain and related symptoms are also associated with physical and emotional trauma including invasive medical procedures. Chronic pain after surgery has until recently been a neglected topic. An extensive literature search failed to produce any references on the general topic of chronic pain after especially open heart surgery. Furthermore, many individuals with depression experience persistent generalized pain and related symptoms.

Objectives: To analyze and compare the frequency of chronic generalized pain and related symptoms in patients with heart bypass surgery (HBPS) and in patients with depression (DEP).

Methods: We evaluated 222 consecutive patients, 126 who underwent coronary bypass surgery during the previous 12 months and 96 with depression. Patients completed a structured questionnaire which included 25 items (generalized pain, fatigue and sleep disturbances, memory problems, tension or migraine headaches, weakness, weight fluctuation, heat or cold intolerance, multiple sensitivities, sense problems, heartburn, abdominal pain, or symptoms of irritable bowel syndrome with yes/no answers. We also analyzed usage of drugs for previous symptoms, smoking, physical exercises, and current status. The study was conducted in 2008.

Results: Individuals with HBPS vs. DEP were older (58 vs. 47 years). Generalized pain was common in both groups (55% in HBPS and 72% in DEP, p=0.103). In general, patients with DEP had more symptoms vs. HBPS. Two thirds of patients in both groups didn't exercise regularly (Table 1). Most of the patients in both groups, HBPS vs. DEP, have a lot of limitations or can't do any of things they want (59% and 73%). Small number of patients used drugs for mentioned symptoms in both groups, HBPS vs. DEP (9% and 37%).

| Generalized pain and related symptoms in HBPS and DEP |
|------------------------|------------------------|------------------------|--------|
|                        | HBPS % | DEP % | p        |
| genpain                | 55     | 72    | 0.103   |
| stressed               | 69     | 84    | 0.105   |
| fatigsleep             | 69     | 87    | 0.274   |
| memory                 | 45     | 84    | 0.001*  |
| migraine               | 57     | 81    | 0.025*  |
| weakness               | 36     | 78    | 0.0001* |
| weight                 | 24     | 50    | 0.018*  |
| coldheat               | 38     | 69    | 0.008*  |
| sensitivity            | 26     | 37    | 0.215   |
| senses                 | 59     | 78    | 0.074   |
| heartbowl              | 59     | 72    | 0.196   |
| smoke_ever             | 71     | 81    | 0.243   |
| smoke_now              | 7      | 56    | 0.0001* |
| exercise               | 26     | 9     | 0.0001* |
| current                | 59     | 73    | 0.07    |
| drugs                  | 9      | 37    | 0.004*  |

Conclusion: Chronic generalized pain and related symptoms are prevalent in many diseases as shown here in patients with heart bypass surgery and patients with depression. These results have important clinical implications including the possibility of the presence of fibromyalgia syndrome in many conditions, often under-diagnosed in clinical practice. A screening tool to recognize this group of patients would be of importance, for diagnosis and early start with appropriate therapies.

Ann Rheum Dis 2009;68(Suppl3):696
Aims: Assessment of disease activity in patients with rheumatoid arthritis (RA) in daily clinical practice is essential in determining the efficacy of the treatment. Especially in ‘tight control’-strategies aiming for low disease activity states or remission, disease activity assessment is essential for good clinical care. In the Netherlands at least, DAS28-guided decision-making is advocated. In daily clinical practice, scoring disease activity of RA, sometimes a discrepancy is found between the severity of pain assessed by the (more) subjective parameters, such as patient’s assessment of global health and TJC and the physician’s impression of the disease activity assessed by (more) objective parameters, such as swollen joint count and ESR. It seems not unlikely that fibromyalgia or a high tender point count (TPC) could account for this discrepancy.

Objectives: To explore the relations between TPC and disease activity score (DAS28) and its individual components, the Health Assessment Questionnaire disability index (HAQ), visual analogue scale (VAS) pain, early morning stiffness, age, gender, and disease duration in patients with rheumatoid arthritis (RA).

Methods: 200 consecutive patients with RA, attending the outpatient clinic, were assessed for disease activity (number of tender and swollen joints, ESR, visual analogue scale for patient’s global health and pain, early morning stiffness, and HAQ), and the number of tender points (according to the ACR-criteria for fibromyalgia). DAS28 was calculated for each patient. Patients were classed into four groups (1-4) according quartiles of disease activity: remission DAS28 < 2.6, low disease activity DAS28 2.6-3.2, moderate disease activity DAS28 3.2-5.1, and high disease activity DAS28>5.1. Spearman correlations were calculated and multiple regression analysis was performed.

Results: 196 patients were eligible for evaluation: 70% was female, had a median age of 59 years, a mean disease duration of 4.2 years, 65% had rheumatoid factor, 90% was on DMARD-therapy, and 51% had active disease, defined as DAS28>3.2. In 14% of the patients, the TPC was ≥ 11. An increase of TPC is seen with increasing of DAS28 class (see figure). DAS28 and TPC were significantly positively correlated (r=0.37, p<0.005), as were TPC and TJC (r=0.40, p<0.005) and TPC and HAQ (r=0.47; p<0.005). In multiple regression analysis VAS pain was a significant independent predictor of DAS28 (p<0.005), but TPC was not. However, TPC was a significant independent predictor of the HAQ score (p <0.002)

Conclusion: Disease activity and the outcome measures DAS28 and HAQ are influenced by coexistence of tender points. When applying DAS-guided individual treatment strategies, further physical examination of the patient is still required, not only to also assess joints not included in the score, such as joints of the feet, but also to not overlook factors, such as tender points influencing the score.

Disclosure of Interest: None declared

[FRI0038] DIAGNOSTIC ACCURACY OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY IN A COHORT OF PATIENTS WITH RHEUMATOID ARTHRITIS AND OTHER AUTOIMMUNE RHEUMATIC DISEASES


Background: The diagnostic accuracy of anti-cyclic citrullinated peptide (anti-CCP) remains partially unproved when tested in a cohort of patients with other autoimmune/inflammatory rheumatic diseases.

Objectives: To define the diagnostic accuracy of the anti-CCP assay in a group of patients with different autoimmune and inflammatory disorders.

Methods: Using a second generation commercial assay (CCP2, Axis-Shield Diagnostics) we tested anti-CCP2 antibodies, in serum samples of 787 patients with clinically proven Rheumatoid Arthritis (RA), 1024 patients with other autoimmune/inflammatory rheumatic diseases (including: 331 patients with connective tissue diseases [CTDs], 447 patients with various inflammatory rheumatic disease, 127 patients with undifferentiated connective tissue disease [UCTD] and 119 subjects with an undifferentiated arthritis [UA]), 298 subjects with no-autoimmune rheumatic disease (247 patients with osteoarthritis [OA], 51 subjects with fibromyalgia), as well as 103 healthy subjects. The optimal cut-off value was determined by analyzing receiver operating characteristic (ROC) curve and it was defined as the value giving the highest accuracy (minimal false negative and false positive results).

Results: A cut-off point of 5 units/ml (as recommended by the manufacturer) was found in 480 out of 787 (61.0%) patients with RA, whereas, in 37 out of 1024 (3.6%) subjects with other rheumatic autoimmune/inflammatory disease and in 5 out of 401 (1.2%) patients with no-autoimmune rheumatic disease/healthy subjects.

Analyzing the ability of anti-CCP2 assay to discriminate diseased cases (787 patients with RA) from 401 normal cases (represented by 103 healthy subjects and 298 patients with no-autoimmune rheumatic disease), we found that the optimal cut-off value was 2.8 units/ml (sensitivity: 65.4%, specificity: 97.5%, positive Likelihood Ratio [LR+]: 26.2). Considering like normal cases patients with other autoimmune/inflammatory rheumatic disorders (1024 cases), the optimal cut-off value for anti-CCP2 was also 2.8 units/ml (sensitivity: 65.3%, specificity: 93.7%; LR+ of 10.3), but a value of 12.8 units/ml had a higher specificity and LR+ (sensitivity: 51.8%, specificity: 98.0%, LR+: 26.2). When we compared new optimal cut-off value for CCP2 (2.8 units/ml) to the manufacturer level (5.0 units/ml), a significant increase of the prevalence of anti-CCP2 positive patients was found in RA (anti-CCP2 findings: 65.4%, increased prevalence: 4.4%, p<0.0001), UCTD (anti-CCP2 findings: 8.7%, increased prevalence: 5.6%, p=0.01) and UA (anti-CCP2 findings: 8.4%, increased prevalence: 5.0%, p=0.03). No statistically significant increase of the prevalence emerged, instead, for CTDs, other inflammatory rheumatic diseases, OA, fibromyalgia and healthy individuals.

Conclusion: The anti-CCP antibody assay is a very valuable tool for the diagnosis of RA. The cut-off value of 2.8 units/ml has the highest diagnostic accuracy with respect to a normal population. When the anti-CCP2 assay is used to distinguish RA from other autoimmune/inflammatory rheumatic disorders, the likelihood ratio is optimal at 12.8 units/ml.

Disclosure of Interest: None declared

Salivary glands are frequently involved in systemic autoimmune diseases. They might be the main target organ in primary Sjögrens syndrome, while clinical features suggestive of secondary Sjögrens syndrome are detected in most of the other connective tissue disorders, and it is feasible that a subclinical involvement might be more common than suspected. If so, saliva could be the ideal milieu to identify potential biomarkers in primary Sjögrens syndrome and in the other connective tissue disorders mirroring the underlying disease processes.

In order to verify this working hypothesis we characterised the salivary proteomic profile of 40 primary Sjögrens syndrome patients (50.86±9.41 years, mean age±SD), 15 patients with secondary Sjögrens syndrome (61.38±10.82 years, mean age±SD), and 40 healthy subjects (48.45±7.56 years, mean age±SD). As pathological controls, the study was extended to 10 patients with Idiopathic sicca syndrome (56.00±10.69 years, mean age±SD), and to patients with other systemic autoimmune disorders and no Sjögrens syndrome: 15 patients with Rheumatoid arthritis (57.62±11.09 years, mean age±SD), 15 patients with Systemic Sclerosis (50.5±12.2 years, mean age±SD), 8 patients with Behçets disease (32±4.30 years, mean age±SD), and 8 patients with Idiopathic inflammatory myositis (55±13.95 years, mean age±SD). The salivary samples were analysed combining two-dimensional electrophoresis (2DE) and matrix-assisted laser desorption/ionisation time-of-flight mass spectrometry (MALDI-TOF-MS). Unstimulated whole saliva samples were collected by spitting directly under standard conditions. The samples were immediately centrifuged for 10 min at 13,000 x g at 4°C to remove particulate material and kept on ice during the process in order to minimize degradation of the proteins. For the 2DE analysis, samples were subjected to isoelectrofocusing in Immobiline Dry-Strip (Amersham Biosciences), pH 3-10L and then processed in second dimension using acryl amide gel (12%) applying a continuous buffer system. The first dimension was carried out using the Ettan IPGphor II (Amersham Bioscience), while the second dimension was done using the Protean II XL Ready Gel-Biorad. Gels were stained with silver and images analyzed with Image-Master2DPlatinum (Amersham Biosciences). Protein spots from each gel were detected, edited manually and matched automatically. Mass spectrometry measurements were conducted with a MALDI-TOF-MS Voyager super STR (Applied Biosystems, Foster City, CA) equipped with a 337-nm nitrogen laser.

The results showed that the protein profiles of primary Sjögrens syndrome and secondary Sjögrens syndrome patients were characterised by a significant decreased of some of the typical salivary proteins including alpha-amylase precursor, carbonic anhydrase VI, prolactin-inducible protein precursor and cystatin SN. At the same time, some other proteins, and specifically calgranulin B, beta-2-microglobulin and IGC1 were significantly over-expressed. These results have been preliminary validated and widened using surface enhanced laser desorption ionisation time-of-flight mass spectrometry (SELDI-TOF-MS). On the other hand, in disease controls without Sjögrens syndrome, we also detected, for each single pathological disorder, a specific combination of biomarkers which could be considered as characteristic to that specific pathology (i.e Rheumatoid arthritis and GRP78/BiP; Systemic Sclerosis and psoriasin; Fibromyalgia and transaldolase). Moreover, applying the SELDI-TOF-MS we also detected a number of peaks with >2-fold changes in the groups of patients affected by Behçets disease and Idiopathic inflammatory myositis with respect to healthy controls.

In conclusion, the proteomic analysis of whole saliva resulted an easy and apparently promising tool to identify pathophysiologic, diagnostic and prognostic markers for Sjögrens syndrome and other systemic autoimmune diseases irrespective of the presence of Sjögrens syndrome. Each single disease seems to be characterised by its specific salivary profile and we are currently investigating the possibility to use this technique to monitor disease activity and response to therapy.

**Authors:** C Baldini1, L Giusti2, C Giacomelli1, F Ciregia2, R Talarico1, C Tani1, E Vesprini1, M Mosca1, L Bazzichi1, G Giannaccini2, A Lucacchini, S Bombardieri1

1Rheumatology Unit and 2Department of Psychiatry, Neurobiology, Pharmacology and Biotechnology, University of Pisa, Pisa, Italy

**References:**


**Disclosure of Interest:** None declared
AN EXAMINATION OF COMORBIDITY IN SLE COMPARED WITH RHEUMATOID ARTHRITIS (RA) AND NON-INFLAMMATORY RHEUMATIC DISORDERS (NIRD)

F. Wolfe¹, K. Michaud², T. Li³, R.S. Katz⁴. ¹Rheumatology, National Data Bank for Rheumatic Diseases, Wichita; ²Rheumatology, University of Nebraska Medical Center, Omaha; ³Outcomes Research, Bristol-Myers Squibb, Princeton; ⁴Rheumatology, Rush University Medical Center, Chicago, United States

Background: Although comorbidity is well described in SLE, there have been no head-to-head comparisons of comorbidity prevalence in SLE and other rheumatic conditions. We used self-report comorbidity from patients participating in a longitudinal study of rheumatic disease outcomes to evaluate comparative comorbidity and the potential contribution of fibromyalgia (FM). Controversy exists regarding self-report measures (Sangha 2003, Hudson 2008).

Objectives: To describe the prevalence of comorbid condition in SLE, to determine the relative risk (RR) of comorbidity in SLE compared with other rheumatic conditions, and to evaluate the effect of FM.

Methods: We evaluated 1,316 community SLE patients, 14,252 with rheumatoid arthritis (RA), and 3,768 with non-inflammatory rheumatic disorders (NIRD), excluding FM, and a comorbidity index was calculated (Michaud 2007). The presence of FM was determined using survey FM criteria (Katz 2006). We determined damage by the newly developed Lupus Damage Index Questionnaire (LDIQ), a self-report version of the ACR/Systemic Lupus International Collaborating Clinics (SLICC) Damage Index (SDI).

Results: The comorbidity index score was significantly increased in SLE 2.6 (95% CI 2.5, 2.7) compared with RA 1.7 (1.7, 1.7) and NIRD 1.9 (1.8, 1.9), and this increase was observed at all age levels and remained significant after non-linear adjustment for age and sex. To test the potential effect of simultaneous fibromyalgia, we examined differences between the comorbidity index before and after adjusting for the presence of FM using survey FM criteria. The presence of FM was associated with a 1-unit increase in the comorbidity index, but did not change the comorbidity scores in the 3 disorders. Survey FM was present in 24.4% with SLE, 17.0% with RA and 14.4% with NIRD. Hypertension (37.4%) and depression (33.8%) were the most common current comorbid conditions among those with SLE. SLE patients differed most from those with RA in RR of current comorbid renal disease (RR 5.7), neurologic disorder (3.7), myocardial infarction (RR 2.8), pulmonary disease (RR 2.3), and stroke (RR 2.0). Patterns were very similar when SLE was compared with NIRD, and in comparisons utilizing lifetime rather than current comorbidity.

Comorbidities in SLE, as measured by the comorbidity index, were most strongly associated with the LDIQ damage score (r=.502) and with SF-36 PCS (r=.383), SF-36 pain (r=.359), and with the Symptom Intensity Scale (FM scale) (r=.331). Associations with correlation coefficients <0.300 included fatigue, patient global, SF-36 mental health, and HAQ disability.

Conclusion: Comorbidity is increased generally in SLE compared with RA and NIRD, including expected cardiovascular and renal conditions. Although more patients with SLE satisfied survey FM criteria, the presence of FM did not alter the increase in comorbidity in SLE. Increase in comorbid conditions is consistent with known increased mortality in SLE.

References:


Disclosure of Interest: None declared

Background: A clearer view was needed on the effects of pain and fatigue for patients with a rheumatic condition in Flanders, Belgium. Mid 2007, ReumaNet vzw started with the development of a questionnaire to find out how big the impact of pain is in daily life. ReumaNet got the support of several patient organisations throughout Flanders.

Objectives: To find out how big the impact is of pain and fatigue in the daily life of people with a rheumatic condition.

Methods: Between January and April 2008 over 6000 people with arthritis/rheumatism received the questionnaire personally either via email or postal letter. A permanent internet link was available on 13 websites. No distinction was made between the different pathologies.

Results: 1624 questionnaires were sent back. Most of the patients who filled in the survey were women, average age around 50. The total group was divided into six diagnosis groups: RA (38%), SA (18%), CTD (8%), PsA (12%), Fibromyalgia (26%) and others. Around 40% of the patients did not think health carers paid enough attention to pain management, more than 40% find it difficult to talk about pain. Nearly 80% experience pain every day, with a peak in fibromyalgia patients (93%). Morning hours seem to be the most difficult time with more pain. Having pain leads to fatigue, less sleep, inner tensions, angerness and even depression and isolation. Only around 30% of the patients think their pain is under control, nearly 40% think it is unbearable. People with pain regret the misjudgements others have about pain and find it hard to talk about it with family, friends, ... Nearly 40% say the pain has isolated them and has great influence on the job opportunities. The high costs of medical treatment are a huge burden to many patients.

Conclusion: Pain is one of the most important aspects of rheumatic conditions and the impact of fatigue is underestimated. Health care providers are not always aware of the effects of pain and fatigue on the patient. These topics need more attention from health carers so the quality of life from people with a rheumatic condition will improve.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):793
A.L. Leong. Patient Advocacy, Bone and Joint Decade, Santa Barbara, United States

Background: Aging and sexuality are important dynamics of the human condition. Yet, it can be difficult for patient organisations to ascertain the latest evidence on both topics as they relate to a person affected by a rheumatic disease. This session will demystify the notions of sex and attend to a topic that does not lose its power with age.

Objectives:

- Review evidence from literature on sexual issues, aging and rheumatic diseases;
- Describe physical intimacy and sexual relations issues faced by rheumatic disease patients;
- Address challenges, practical options to overcome barriers to intimacy and sexual relations; and
- Identify communication strategies to assist staff and volunteers of patient advocacy organisations to deal effectively with sensitive issues.

Methods: Extensive review and summary of evidence-based data of the effects of osteoarthritis, rheumatoid arthritis, scleroderma, fibromyalgia, Sjogren's syndrome, Reynaud's, lupus, juvenile arthritis, and their medications on aging and sexuality. The presentation incorporates evidential problem-solving strategies from other chronic disorders, such as heart and cancer. This presentation was an invited one-hour lecture at the 2008 Scientific Meeting of the American College of Rheumatology.

Conclusion: Understanding the potential impact of rheumatic disorders on the natural human functions of aging and sex is an important, yet little discussed factor in helping persons affected by these disorders. The presentation will offer effective, evidence-based strategies to members and staff of patient advocacy organisations to assist their constituents about sensitive subjects such as sex and sexuality.

Disclosure of Interest: None declared.

Ann Rheum Dis 2009;68(Suppl3):792

Ann Rheum Dis 2009;68(Suppl3):759
Objectives: To demonstrate that a collaborative Rheumatology Multidisciplinary Assessment Clinic (MAC) improves access to care and management for patients with non-inflammatory musculoskeletal conditions.

Methods: Patients referred to our Division of Rheumatology Central Referral with symptoms suggestive of a non-inflammatory musculoskeletal condition wait an average of 52 weeks for review by a rheumatologist. To reduce this wait time we developed a MAC where these patients are scheduled with our Nurse Practitioner (NP) and Physiotherapist (PT). After a complete history and physical examination is performed, a management plan is developed. The plan includes blood tests and diagnostic imaging as needed. Each patient receives education regarding their condition and is provided with basic rehabilitation advice as needed. Referrals are made as needed to community-based rehabilitation programs and social services. Patients found to have complex conditions are referred to the clinic’s consulting rheumatologist. Patients may also request consultation with the rheumatologist. The NP sends consultation reports to the referring physicians and to the clinic’s consulting rheumatologist.

Results: From July 2008 to January 2009, 50 pts were evaluated at the MAC. The average wait time was 19 weeks. The average age was 48 yrs (21-81 years). Female to male ratio was 3.54:1. Thirty-two patients were employed, 7 retired, 5 on disability and 6 were unemployed. The referring diagnoses included fibromyalgia (FM) in 12 patients of whom 11 had a similar post-assessment diagnosis. One required investigation for a possible sleep disorder. Eleven patients had a referring diagnosis of OA and of these 8 had similar post assessment diagnoses. One patient had psoriatic arthritis, 1 had spinal stenosis and 1 had intermittent claudication. Five patients were referred with abnormal serology. Two continue to be followed and one patient was referred to a dermatologist. Fifteen patients were referred for assessment of polyarthritis. The post assessment diagnoses included OA, Ankylosing Spondylitis (AS), DISH, ulnar neuropathy, FM, hypermobility syndrome, subacromial bursitis, tendonitis, carpal tunnel syndrome (CTS), plantar fascitis, seronegative inflammatory arthritis, gout and possible inflammatory arthritis. One patient had neutropenia and was referred for further testing. Four patients were referred with back pain and the post assessment diagnosis was unchanged but comorbid conditions were found in 2 patients. One patient had CTS, and 1 had FMS. Three patients were evaluated for monoarthritis. Two had osteoarthritis and one had possible inflammatory arthritis requiring further testing. Four patients in the entire group had inflammatory arthritis. Sixteen patients were referred to community-based rehabilitation services; 1 to a dietician, 1 to home care, 2 to orthopaedic surgery, 1 to plastic surgery, and 1 to haematology. Two patients with back pain requested consultation with a rheumatologist.

Conclusion: The development of this clinic is in its early phase. To date we have expedited the care of a number of patients. Patients are satisfied with their care. This type of collaborative multidisciplinary clinic can facilitate access to care.

Disclosure of Interest: None declared

Ann Rheum Dis 2009;68(Suppl3):781